PSJ3

Exhibit 674E

In *City of Jennings Police Department v. Dorr*, for example, the claimant suffered from chronic pain and depression due to a severe back injury. She had tried a variety of drugs, and her physician finally prescribed morphine sulphate for pain relief -- specifically, 180 milligrams every eight hours, a dose usually reserved for chronically or terminally ill cancer patients. The court noted that the medical literature supported long-term treatment in certain cases with high dosages, although there was a split of opinion in the medical community. The court found that the level of drugs prescribed was not excessive and upheld the treatment plan of the physician as appropriate.[91]

Courts in a variety of cases -- malpractice, workers compensation, and medical discipline, for example -- apply a standard increasingly calibrated to proper pain management practices. As long as the physician can present evidence of a thoughtful program of pain management for a particular patient, the courts are willing to respect aggressive opioid use.[92]

C. Other tort norms forcing pain management

1. Referrals to pain specialists

Multidisciplinary pain programs are acknowledged to provide cost-effective approaches to pain.[93] The ideal program includes specialists who can provide a range of services, including an anesthesiologist, a behavioral medicine specialist, a physical therapist, rehabilitative medicine specialist, and case managers to oversee and coordinate care.[94] Consequently, it is necessary for the primary care physician and other specialists to be familiar with the existence and expertise of a pain specialist. This is more than a statement of medical necessity for the patient; established tort principles require a physician to make a referral to the appropriate specialist when the physician lacks the knowledge or experience to properly treat the patient.[95]

In *Freeman v. Cleveland Clinic Foundation*,[96] the plaintiffs' son committed suicide. They argued that the surgeon who was treating the young man for his knee injury negligently failed to refer him to a pain management clinic after he concluded that the patient would not benefit from further physical treatment of knee problems. The court held that failure to refer did not proximately cause the young man's death, a common judicial way of avoiding the imposition of liability for suicide. The court did not, however, reject the possibility of such a duty to refer. In a more typical malpractice case, where a patient is experiencing acute or chronic pain and the treating physician fails to treat it because of a lack of pain management knowledge, it is more likely that a duty to refer will be found. For instance, in *Johnson v. Kokemoor*,[97] a Wisconsin informed consent case, the court held that the physician's inexperience with a surgical procedure should have led him to offer the patient the choice of a referral to a nearby experienced surgeon.

The common law tort duty to refer is a well-established one. As the specialties of pain management mature, physicians who do not want to manage their patients' pain have a duty to refer. Patients with complicated pain imbedded in their disease process, like many cancer patients, require pain management as an integral part of their treatment. A pain management specialist must therefore be a part of the treatment team at a minimum. A physician who refuses either to treat the pain in conformity with current guidelines or to refer the patient is acting unethically. One could even argue that refusal to treat a pain patient is analogous to refusing to treat HIV-positive patients. The duty to refer must be carefully developed in light of the problem of pain, typically imbedded in the disease process for many patients. It can be argued that a primary care physician in particular must become familiar with pain management treatments, since referral may not always be possible -- either because of insurer limitations or physical proximity. In such cases, the duty of continued treatment binds the physician to learn about pain and its control, or risk an action for abandonment of the patient.

2. Negligent or intentional infliction of mental distress

Can a patient or the family as bystanders sue for infliction of emotional distress because of the patient's tangible suffering unrelieved by proper pain management? The family members of a post-operative patient, or a terminally ill patient, are vulnerable, worried, and anxious. Visible suffering, unrelieved by the tools of pain management, can predictably create emotional distress in family members. Witnessing a family member in a hospital or nursing home suffer from unrelieved pain is itself painful.

No case law exists to support such a duty toward family members, but it can be movingly and persuasively argued. Courts have allowed plaintiffs to sue health-care providers for the negligent infliction of emotional distress under particularly egregious circumstances. One example is *Oswald v. Legrand*.[98] The plaintiffs, a

married couple, sued for mental injury as the result of a series of obstetric events. The wife was pregnant and began to have difficulties prior to her five-month check-up. She was admitted to the hospital, where she was treated rudely by physicians and staff and finally gave birth to a child who was presumed to be stillborn but turned out to be alive. The sequence of events was outrageous. The Oswalds claimed, among other things, severe emotional distress and mental anguish caused by witnessing the negligent treatment of their newborn infant. The court observed that tort law allows recovery for emotional distress when it is connected to physical injury or "where the nature of the relationship between the parties is such that there arises a duty to exercise ordinary care to avoid causing emotional harm.... [W]e think liability for emotional injury should attach to the delivery of medical services" (emphasis added).

Oswald focused on the vulnerability of the plaintiffs, coupled with the "crass insensitivity" of the medical staff. A similar case is *Wargelin v. Sisters of Mercy Health Corporation*,[99] where a series of obstetric disasters befell the plaintiffs. The obstetrician made only two visits during labor, even though a Caesarean section was indicated due to the plaintiff's lopsided uterus and the fact that the fetal monitor indicated distress. The staff failed to react, and an intern subsequently delivered the plaintiff's child, not breathing and blue in color, and placed it on the mother's stomach as if it were a healthy child. Realizing the child's condition, the obstetrician then grabbed the child and began to pound on her chest and administer electrical shocks to revive it. A call for a pediatrician to help went unanswered, and after fifteen minutes, the rescue attempt was abandoned. The Michigan court applied the bystander rule, which permits a family member witnessing an injury to a third person to recover if the family member is present or suffers shock "fairly contemporaneous" with the accident. The court held that "the cumulative effect of all the events surrounding the stillbirth of the child, if proven to be negligent at trial, are sufficient to cause a parent to suffer emotional and mental distress."

In these cases, the courts have required observation of the disturbing events.[100] "Observation" has been liberally construed by some state courts to include a discussion with a physician about a loved one's deteriorating condition.[101] Most courts, however, require some direct observation of the events causing the bad outcome, not just observation of the bad outcome itself.[102]

Some jurisdictions are reluctant to allow observational distress, fearing a litigation explosion and difficulties of proof in such cases. In *Gray v. INOVA Health Services*,[103] a mother sued a hospital for negligent infliction of emotional distress after seeing her young daughter's physical reactions to an overdose of drugs during a medical test. The plaintiff alleged that she contemporaneously experienced extreme shock, blacked out, fell to the floor, vomited, and still suffers from mental anguish. The court affirmed a demurrer for the defendant on the grounds that the hospital owed no duty to the mother, only to the child who was the patient. However, Gray is distinguishable from the Oswald case, where active labor and its stresses involved both parents intimately in the birth process and where the staff's behavior was reprehensible. In Gray, the fault lay in a negligent dosage of drugs, not a cascade of rude and insensitive behaviors directed at vulnerable parties.

The doctrine of negligent infliction of emotional distress, therefore, has the potential to offer a remedy to vulnerable family members as they watch a loved one suffer needlessly in pain. The analogy to the labor and delivery cases is clear in the hospital or nursing home setting where the patient is obviously suffering. The doctrine is arguably applicable to any instances of intractable pain and its poor management in extreme cases.

3. The doctrine of informed consent

Can a plaintiff argue that informed-consent doctrine requires that pain management be disclosed as an alternative treatment to doing nothing for intractable pain, even if the physician does not want to use. opiates or otherwise manage the pain? Such an obligation is connected to the duty to refer discussed above.

Physicians are required to disclose alternative methods of treatment-- along with their risks and consequences, and their probability of success -- if these methods of treatment are generally acknowledged within the medical community as feasible.[104] Physicians are obligated to discuss with patients the side-effects of drug treatments where driving or other life activities might be impaired.[105] Some courts have held that alternatives should be disclosed even if the alternative is more hazardous[106] or the physician is not capable of performing the procedure or evaluating its risk.[107] The threshold is only that the alternative treatment be considered within the standard of care.[108] Such alternatives might include access to pain control programs or other specialty services.[109] Aggressive pain management through opioid prescription is, at present, at least a minority practice within the medical professions using comprehensive pain management strategies.

The definition of "treatment" for purposes of when "informed consent" is needed has been construed broadly to include diagnostic options and choices of hospitals for performing a procedure. Physicians must disclose diagnostic procedures that might assist patients in making an informed decision about treatment. In *Martin v. Richards*,[110] the physicians failed to inform the parents of a minor patient of the availability of a CAT scan to detect intracranial bleeding and the unavailability of a neurosurgeon at the hospital to operate on the child. The court held that it was for the jury to decide whether these things caused the patient's brain damage.

In *Vachon v. Broadlawns Medical Foundation*,[111] the plaintiff suffered severe multiple trauma injuries. The issue was whether the plaintiff's transfer to a university hospital two hours away instead of to closer trauma hospitals was reasonable. The court held that the decision to transfer was part of the patient's treatment and raised an issue of reasonable care. In *Johnson v. Kokemoor*,[112] the court included within a surgeon's duty of disclosure an obligation to inform the patient of the proximity of experienced providers in a nearby clinical setting who would have been able to perform the operation at a lower risk.

The corresponding pain management issue is whether a physician should be sufficiently aware of choices -- hospices for cancer patients, pain management programs for nonmalignant pain sufferers, or other physicians trained in modern pain management techniques -- to be able to inform a patient of his or her options in treatment. It does not seem a stretch to require a duty to inform patients in such circumstances that a full range of pain therapies is available. Failure to discuss pain management options and the possibility of referral or transfer might well appear as a count in the patient's malpractice complaint for pain mismanagement.

D. Proving pain as damages

Present and future pain and suffering is a legitimate component of a damages claim by a malpractice plaintiff. As Dobbs says, "[t]he pain for which recovery is allowed includes virtually any form of conscious suffering, both emotional and physical."[113] This can even include the pain of recalling past pain.[114] Pain experts can testify about such pain, as can the plaintiff; inferences about the degree of pain can also be drawn from the nature of the plaintiff's condition and the kind of medical treatment needed. Pain includes the sensation of physical pain.

In the normal tort case, pain is the result of a bodily injury caused by the defendant. The court is willing to instruct juries on pain and suffering when the plaintiff has suffered tangible injury due to the defendant. In the medical setting, pain from a missed diagnosis and lost opportunity to treat can be part of damages. The pain management failures are more complicated: The physician or provider is responsible not for the patient's condition, but for the mismanagement of pain, which is a by-product and symptom of an underlying disease. Pain, therefore, becomes the only component of damages, by analogy to the mental distress torts. The loss of enjoyment of life, as a corollary of the pain, may be allowed as a separate component of damages. The plaintiff's reactions to the pain and his or her sense of loss as a result may also be compensable.[115]

III. INSTITUTIONAL FAILURES TO MANAGE PAIN: THOUGHTLESS SYSTEMS

Pain is ignored in the institutional setting as well as the physician's office. The consequence of unrelieved pain, particularly cancer pain, is not only patient suffering and decreased quality of life. It has been estimated that "[b]etween 30 and 50 percent of cancer patients in active treatment and 70 to 90 percent of those with advanced disease experience moderate to severe pain...."[116] In surveys of surgical patients, it has been found that approximately half of all hospitalized post-operative patients failed to receive adequate pain relief. Patients reporting moderate to high levels of pain received less than half of the pain medication that was ordered.

The result of this undertreatment is decreased quality of life, functionality, activity, appetite, and productivity. The patient, having experienced such severe pain, can also become unwilling to continue treatment and become suicidal. At the MD Anderson Cancer Center in Texas, the annual hospital costs for pain admissions are estimated at $4.7 million annually.[117] Most of this pain can be managed by proper assessment of causes and treatment with opioid analgesics.[118] And most of this pain is found in patients in institutional clinical settings -- general medical, surgical, and oncology wards; burn units; emergency departments; and pediatric wards.[119]

Failures of pain management can have catastrophic consequences for patients and for health-care institutions. Undertreatment may also lead to patient suffering, surgical complications, and other negative treatment results. Pain is not just a background noise produced by a disease like AIDS or cancer, to be stoically ignored or endured; it is the cause of somatic failures and expensive hospitalization and of patient resistance to treatment. Lower back pain, as one example, costs millions of dollars a year in loss work time. Pain, in other words, operates as an

independent medical condition, and its continuation when modalities of treatment are available is iatrogenic -- that is, injury that is provider-induced.[120]

Malpractice tends to isolate the individual physician as the cause of patient injury and suffering. The evidence as to undertreatment suggests that while physicians may often be at fault, it is primarily the system of care that has failed to reorganize its resources to address the problem. Since educational approaches lack efficacy, the better approach is to affect the systems that influence physician behavior.

Treatment and management of pain by institutional providers can be fostered by the possibility of liability for failure to satisfy a standard of care for effective pain relief. These threats of litigation can be powerful incentives to counteract physician resistance to the adoption of sound pain management practices.

A. Hospitals: the mandate of pain management

In the hospital setting, unnecessary patient pain frequently imposes higher costs as the result of lost wages and higher health-care utilization, such as emergency room visits and unnecessary hospitalizations.[121] The hospital system has not been designed to recognize pain as a valid indicator of suffering and track and treat it with the intensity with which a fever is treated in a hospital. "[R]eports of unrelieved pain do not invariably result in corrective measures; pain may not be visible at the coordinating centers of the ward, and physicians and nurses have not traditionally been held accountable for providing titrated analgesia."[122]

1. The general duty to manage complex systems

Hospitals have been slow to adopt pain management practices. Hospital staffs have not made pain relief a priority, and hospital organizational structures have failed to incorporate pain management support.[123] For instance, the SUPPORT Study in 1995 found that hospital treatment for dying patients involved poor communication between physicians and patients, overly aggressive treatments, and inattention to patient pain and suffering. It provided a discouraging indictment of the hospital system -- namely, that it failed to treat patients with pain at the end of life. Critically ill patients were and continue to be bombarded with the newest medical technologies to extend their lives, even in the face of their stated wishes for a prompt relief of pain and suffering. A recent study of hospital palliative care concluded that lack of financial reimbursement is one of the reasons that end-of-life care is not a priority for hospitals.[124]

Guidelines from the Agency for Health Care Policy and Research (AHCPR) provide for the minimization of the incidence and severity of acute pain.[125] These guidelines were published in 1992, but "evidence suggests that suitable pain management programs have yet to be developed."[126] This is despite the fact that the technologies are available, including intraspinal opioid administration, opioid infusion, and inhalational analgesia,[127] and that the organizational structures are well-defined.[128]

Hospital-based clinical management has neglected postoperative pain. In the words of Blau and colleagues, "[r]ecent data suggest that many patients continue to fear severe pain after surgery, and many post-operative patients continue to have significant pain. Further improvements in the quality of pain control will not occur unless it is recognized as a priority by health care providers, and an institutional approach is taken to assure that high quality analgesic care is consistently provided."[129] In spite of sound guidelines, "many health care institutions continue to lack any organized institutional approach for the management of acute pain."[130]

Yet the benefits of pain management are apparent. Surgical outcomes are improved by effective post-operative pain management, which may also reduce patient time in an intensive care unit, accelerate discharge readiness, and reduce the overall cost of hospitalization. These outcome benefits are based on inhibition of the metabolic stress response after surgery. Evidence shows that inadequate control of pain can also interfere more directly with recovery by impairing pulmonary function and movement and delaying the recovery of gastric and bowel function.[131]

Many medical disciplines are responsible for pain management. Pain management needs to be an institutional priority, supported with resources and leadership.[132] A health-care institution, whether a hospital, nursing home, or clinic, is liable to its patients for negligence in maintaining its facilities, providing and maintaining medical equipment, hiring, supervising and retaining nurses and other employees, and failing to have procedures in place to protect patients.

Basic negligence principles govern hospital liability for injuries caused by something other than the negligent acts of the medical staff.[133] Hospitals are generally held to a national standard of care for hospitals of their size and treatment category. Where, however, a new technology of proven efficacy has been adopted by some hospitals, the standard may be used to measure the practice in all hospitals.[134]

The professional duty of a hospital is to provide a safe environment for patient diagnosis, treatment, and recovery. If an unsafe condition on the hospital's premises causes injury to a patient as a result of the hospital's negligence, the hospital has breached its duty qua hospital.[135] The test is "whether the negligent act occurred in the rendering of services for which the health care provider is licensed."[136] Hospitals must have minimum facilities and support systems to treat the range of problems and side effects that accompany the procedures they offer. Equipment must be adequate for the services offered, although it need not be state of the art.[137]

Pain management requires a systematic team approach. Much of the case law that has articulated hospital responsibility has come to focus on the administrative and treatment systems in place. For example, short staffing has been rejected as a defense where the available staff could have been juggled to achieve closer supervision of a problem patient.[138] Failure to provide an adequate twenty-four hour anesthesia service also may create liability.[139] A hospital and its contracting physicians may be liable for damages caused by inadequate or defective systems they develop and implement, particularly where emergency care is involved. Poorly designed systems can create harm just as readily as an incompetent staff member.[140] Hospital on-call systems must work properly,[141] and systems for storing and supplying medications must function effectively.[142] Another example of such an administrative failure is when a hospital fails to properly schedule a specialist consultation once it has been requested by a staff physician.[143]

Hospitals will be liable for injuries caused by inadequacies in the internal programs that are mandated by statutes.[144] Once a hospital assumes a new responsibility, even a voluntary one, it is expected to properly implement that responsibility.[145]

2. Corporate negligence

Courts have expanded the doctrine of corporate negligence for hospitals since the 1960s, recognizing that the hospital is no longer just a shell for the physician to use, but an active ring leader in providing care, support, and service. A hospital is thus directly liable for the failure of administrators and staff to properly monitor and supervise the delivery of health care within the hospital. A hospital has a non-delegable duty that extends directly to its patients, and it is liable for a breach of these duties. The liability arises from the hospital's action or inaction regarding its policies, rather than the specific negligent acts of one of its employees.[146]

The courts have generally required hospitals to provide surveillance of the quality of patient care within the hospital.[147] Other courts have imposed on hospitals a duty to follow their own internal procedures[148] and to monitor the risks to patients created by poor treatment by staff physicians.[149]

Corporate negligence imposes liability on health-care institutions for their failure to protect patients from the harms the institution could have controlled. The doctrine's best recent formulation is found in *Thompson v. Nason*, decided by the Pennsylvania Supreme Court.[150] The court held that corporate negligence is a doctrine imposing liability on a hospital if it fails to uphold the standard of care to "ensure the patient's safety and well-being while at the hospital." Four areas of liability are involved:

- a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment;[151]
- a duty to select and retain only competent physicians;
- a duty to oversee all persons who practice medicine within its walls as to patient care; and
- a duty to formulate, adopt, and enforce adequate rules and policies to ensure quality care for patients.

This articulation of the doctrine of corporate negligence by the Pennsylvania Supreme Court is broader than that of other state courts considering the issue; these other courts have often limited the doctrine to the duty to select and monitor physicians and allied health-care professionals. Thompson expands the scope of the doctrine to encompass the hospital's general duty to ensure quality of care for patients. This recognizes the complexity of the modern health-care institution and the need to impose a patient-centered approach to doing business. The fourth duty articulated -- to formulate, adopt, and enforce adequate rules and policies to ensure quality care for patients --

is directly relevant to pain management. If a standard of care is established by accreditation standards, then a hospital can be expected, independent of accreditation, to follow such standards.

a. Duty to properly select and retain medical staff

Most jurisdictions have held hospitals to a duty to take reasonable steps to ensure the competence of its medical staff.[152] The monitoring and retention of hospital staff have led to expanded duties to detect incompetence. A properly designed utilization review process within an institution will produce data as to unnecessary procedures, high error rates, and other early warnings of problems with a staff physician. The existence of such a process will give a hospital actual notice of possible incompetence, exposing it to liability if it fails to act to deal with the problem.[153]

In addition to determining which staff physicians are incompetent to handle certain procedures, the hospital must detect any concealment by its staff of medical errors.[154] While some courts have limited this duty to only those situations where a hospital has learned of physician insufficiencies,[155] others have talked of "negligent supervision" in terms of an affirmative duty to detect problems.[156] The few cases that reject a hospital's duty to monitor are increasingly outside mainstream jurisprudence on hospital responsibility.[157]

Pain management obligations should be shouldered by physicians, with continuous feedback and attention to the level and quality of such management by the hospital. A failure to provide training and feedback and to detect physician reluctance to use proper techniques provides an argument of corporate negligence.

b. Duty to formulate, adopt, and enforce adequate rules and policies to ensure quality care

The broad statement of this fourth duty of hospitals, as articulated in *Thompson v. Nason*, properly defines the role of corporate negligence in addressing institutional management of all dimensions of patient care. The regular charting of pain should be treated as a "fifth vital sign" along with the other vital signs of temperature, pulse, respiration, and blood pressure.[158] Pain management is now a dimension of hospital administration in light of the new JCAHO standards. The duty to monitor patient care to ensure that staff physicians are properly treating patients must now include proper pain management.

i. JCAHO standards and pain management as a priority

Hospitals are regulated by their states, and state regulation typically defers to the standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The standard of care applied by courts in malpractice actions also reflects a baseline mandated by JCAHO standards, including its peer reviews through internal committee structures. Courts have consistently allowed evidence of JCAHO standards, state hospital licensure laws, and the hospital's own by-laws, which the trier of fact is entitled to accept or reject, as creating a permissive inference of negligence[159] or a rebuttable presumption.

Failure to follow new JCAHO standards for pain management can thus lead to liability, with such standards being admissible as evidence of the standard of care once they are implemented for the hospital's accreditation.[160] The standards force integration of pain management into a hospital's overall care of a patient. A team approach to medical practice, incorporating pharmacists and other providers, is likely to further reduce risks. The standards developed by JCAHO and the National Committee on Quality Assurance need to rapidly incorporate the current findings of the Institute of Medicine report, To Err Is Human: Building a Safer Health System, and increase the pressure on individual and institutional health-care providers to redesign their systems to reduce risk.

Only within the last few years have JCAHO standards finally addressed pain management in hospitals and the need for proper organizational structures to promote such management. In 1991, JCAHO mandated that pain be routinely assessed and outcomes of care be routinely documented for terminally ill patients, but not for other patient populations experiencing acute or chronic pain. By 1995, JCAHO had written pain management into its guidelines. Finally, with the 2000 and 2001 editions of the JCAHO accreditation manuals, JCAHO now requires surveyors inspecting hospitals to include in their surveys a systematic look at pain assessment and management; the surveyors must determine whether the hospital has integrated compliance with the pain management standards with the overall care of patients.[161]

If proper pain management is now part of the hospital accreditation process, then corporate negligence suits will use such accreditation guidelines, along with common law decisions that generally impose a duty of institutional responsibility for patient care, to establish the hospital's standard of care.

ii. Emergency Medical Treatment and Labor Act (EMTALA)

The Emergency Medical Treatment and Labor Act,[162] or EMTALA, provides another source of liability that particularizes the standard of care expected of hospitals that participate in the federal Medicare program[163] and have emergency departments. The Act requires covered hospitals to provide a medical screening examination[164] to any patient coming into the emergency department[165] of the hospital.

The question from the perspective of pain management is twofold: Is pain an emergency medical condition that requires stabilization before transfer is possible? and Is avoidable or treatable pain a material deterioration of the patient's condition? The control of avoidable physical pain is a significant obligation of medical treatment. Severe physical pain that could have been avoided with appropriate medical care is arguably a material deterioration of the patient's condition.[166]

If an emergency medical condition[167] is present, the hospital must provide treatment to stabilize[168] the patient's medical condition unless the patient requests the transfer in writing, or a physician certifies that the benefit of the transfer to the patient outweighs the risk.[169] If the hospital transfers the patient,[170] the transport support provided must meet the statutory standards for adequacy of equipment and personnel, the receiving facility must agree to accept the transfer, and the transferring hospital must provide all medical records to the receiving facility.[171] Patients may refuse treatment, may refuse to consent to the transfer, and may request transfer.[172]

EMTALA provides for a private cause of action for violation of the statute. Any individual suffering harm as a "direct result" of a hospital's violation of the statute has a cause of action against the hospital.[173] The statute also provides for civil monetary penalties against the hospital and against the "responsible" physician for violations of the Act.[174] The statute provides that civil damages[175] for a hospital's violation of the Act shall be "those damages available for personal injury under the law of the State in which the hospital is located."[176] Although claims under EMTALA are not claims for medical malpractice, plaintiffs usually claim both a violation of EMTALA and medical malpractice.

The Act provides that "if any individual ... comes to the emergency department,"[177] it is the hospital's duty to assess whether the patient has an emergency medical condition.[178] The claim of failure to provide an appropriate medical examination requires that the patient be physically present in the emergency department, but some courts have held that a claim of transfer in an unstable condition does not require that the patient enter the hospital through the emergency room.[179]

Courts interpreting EMTALA's medical screening requirement have generally adopted a standard of differential treatment and not professional standards. Plaintiffs must prove that the hospital's policy is to conform with professional standards. To the extent that the hospital has established written guidelines or has followed consistent practices in emergency medical examinations, it is, of course, essential for plaintiffs to prove their content.[180) The patient's examination may be so cursory or inadequate as to amount to no examination at all, resulting in a finding that EMTALA was violated.[181]

A hospital violates the Act if it fails to provide an "appropriate medical screening examination" to the patient arriving in the emergency room. If the hospital provides an appropriate examination that detects an emergency condition or if the patient's emergency condition is otherwise known to the hospital, the hospital is liable under the Act if it transfers or discharges the patient in an unstable medical condition. Courts have required the plaintiff to prove that the hospital actually knew of the plaintiff's emergency condition in order to trigger the duty to stabilize prior to transfer or discharge.[182] Where the hospital lacks actual knowledge of the patient's emergency condition as a result of a statutorily inadequate medical screening examination, the hospital would be liable at least for violating the examination requirement of the Act.[183]

Courts look at several factors in deciding whether a patient was stable before transfer or discharge. If the hospital actually admitted and treated the patient for a significant amount of time, this is some evidence of stability.[184] Patient stabilization must be judged from the perspective of professional standards rather than standards established by each hospital.[185] The Act explicitly defines "stabilized" as a condition in which "no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer."[186]

The EMTALA action is a small piece of the liability package for pain mismanagement. No case law has yet developed such a theory with regard to pain. But recognition of the importance of pain management in the new JCAHO pain management guidelines means that hospitals that seek JCAHO accreditation will need to develop policies for assessing and treating patient pain, including emergency admissions. This then sets a standard that must be followed in screening patients and stabilizing them. EMTALA then offers a statutory basis for suit in emergency admissions when patients are not properly screened or stabilized for pain.

B. Managed care organizations: paying for pain relief

Managed care organizations undertake to "manage" the care of subscribers. For outpatient conditions, such as lower back pain or other kinds of disability that can result in chronic intractable pain, it is arguable that a managed care organization should be responsible for designing and paying for institutional approaches to proper pain management. If clinical guidelines describe an ideal approach to pain, then the individual or institutional health-care provider is responsible for implementing such a strategy. Cost-sensitive managed care organizations, however, may resist.

For example, emergency room treatment for pain is likely to be resisted by utilization reviewers, arguing that it is too subjective and will impose excessive costs on the plan. Likewise, hospice care for cancer or other patients at the end of life is not provided consistently by all managed care organizations.[187] Nonmalignant chronic pain, such as that experienced by nursing home residents or those with other disabilities, can be expensive to treat with some of the new treatment approaches and is often neglected because of difficulty in defining it.[188] The complex sources of chronic nonmalignant pain make diagnosis and management difficult. As a result, patients with such pain may need extensive diagnostic tests and referral to specialists or multidisciplinary centers.[189]

Managed care plans are worried about the costs of proper pain management, and with some justification. Susan Wolf notes:

> Just as research on pain is in its infancy, research on how well or poorly MCOs [managed care organizations] do in treating pain similarly seems to be at an early point. It is clear that "HMOs' outpatient prescription drug benefits frequently are subject to restrictions ... such as generic substitution, therapeutic substitution, and [limited] formularies." Moreover, these benefits may be available in some HMOs only by subscriber purchase of an extra "rider" to the coverage contract, and coverage affects access to pain-relieving drugs. Much remains to be determined about the effectiveness of MCOs in addressing pain, however, especially for patients at the end of life.[190]

Managed care organizations and insurers are reluctant, in large part, because they feel that many of the pain management guidelines are not based on extensive clinical studies.[191]

Until recently, courts have held that ERISA (the Employee Retirement Income Security Act) preempted most litigation against managed care organizations for medical errors. But this position has been deteriorating in the face of quality-of-care abuses by managed care organizations. At bottom, managed care organizations are businesses. They market their care to potential employers and subscribers in a competitive marketplace for health care. They recruit and organize their physicians through their networks. They design a corporate system in which health care is delivered. And they must administer this system in a safe fashion that avoids injury to subscribers caused by the negligence of plan physicians and other providers. Malpractice claims based on vicarious liability, corporate negligence, negligence per se, and intentional inflection of mental distress may be allowed to proceed against managed care organizations under the current law as quality-of-care issues outside the scope of an ERISA claim for benefits (i.e., quantity-of-care, or coverage, issues).[192]

1. Agency doctrine

Under theories of agency, managed care organizations may be on the hook for the liability of the physicians and other providers who work for them. Such vicarious liability has been upheld by the majority of courts, having considered the question of liability not to be preempted by ERISA.[193] The reason is that the managed care organization's plan is irrelevant to the claim, since the claim of agency does not rise and fall with the plan.[194] Rather the claim is established by reference to the parties' reliance and representations, a question of fact not involving the interpretation of an ERISA plan.[195] If, however, the underlying claim against the treating physician is a failure to treat -- a denial of benefits -- then it relates to the benefits plan, and the claim could not be resolved without reference to a determination on benefits. In such a situation, one circuit court has held that ERISA completely preempts the agency claim.[196]

2. Substandard plan design and administration

Claims of negligent design and administration of the delivery of health-care services have been allowed in recent cases.[197] A negligence claim against a plan for providing contractual benefits in "such a dilatory fashion that the patient was injured are intertwined with the provision of safe care."[198] In *Pappas v. U.S. Healthcare*, the issue was a delay in transporting the plaintiff to a specialty trauma unit for care. The delay arguably was caused by the utilization review process of the managed care organization, which did not allow transport to the best hospital unit in the area for spinal injuries. The case appears to involve both a system-induced delay and a benefits question as to which hospitals were available to the plaintiff. The case was remanded by the U.S. Supreme Court for reconsideration in light of its decision in *Pegram v. Herdrich*. Absent ERISA preemption as a defense, the doctrine of corporate negligence could be held to apply.[199]

A claim that a ERISA managed care plan is "substandard" and has led to patient injury as a result has been allowed to avoid ERISA preemption. In *Moreno v. Health Partners Health Plan*,[200] the District Court held that there was "no relation between an action for medical malpractice and the recovery of benefits or the clarification of rights to future benefits under an ERISA plan."[201] An action for negligent supervision of plan physicians has been allowed by courts to proceed as a quality issue and has not been deemed preempted by ERISA.[202] Likewise, a plan decision to discharge a patient from the hospital to her home rather than a skilled nursing facility has been considered a "quality" issue, not suitable for preemption.[203]

Where a plan is responsible for the continuum of care and it proves to be inadequate -- even if that means it refuses to cover a benefit at a rehabilitation hospital or other facility -- courts have found this to be a complaint of substandard care and thus not preempted by ERISA.[204] If a plan is negligent in failing to provide appropriate screening tests and studies, this, too, could be viewed as a negligent provision of benefits and not a denial of benefits, thus subject to ERISA.[205] The U.S. Supreme Court's recent decision in *Pegram v. Herdrich*[206] further opens the door to state tort litigation against managed care organizations on all the theories that hospitals are subject to, by refusing to interpret ERISA as imposing a fiduciary duty on physicians making "mixed eligibility decisions."

The problem with managed care organization liability is that pain management is still in its infancy. The field lacks clinical practice guidelines that are well-grounded in clinical studies. The practitioners of pain management are credentialed by different organizations and the lack of a consensus as to the gold standard for accreditation means that managed care medical directors are properly uncertain about to whom patients should be referred. Evidence of fraud in hospice billing in some cases has exacerbated managed care organization reluctance. As Diane Hoffmann writes:

> additional resources and attention need to be devoted to developing guidelines for treatment of various types of pain and ... more research needs to be conducted on the effectiveness and cost effectiveness of various pain treatment modalities and palliative care.... Additionally, there needs to be broader recognition of what constitutes a pain specialist and when a referral to a pain specialist is appropriate.... [U]ntil more widespread consensus develops on what constitutes effective treatment of pain, especially chronic pain, or agreement on credentials for certification of pain providers, we can expect insurers and MCOs to be reluctant to approve coverage of some forms of pain treatment and continuing variation across plans in the way they deal with this issue.[207]

Managed care plans should be expected to be a market for effective pain management practices, since the use of the "substandard" test by the federal courts suggests not only an ERISA preemption defense for plaintiffs, but the emergence of a corporate negligence test that applies directly to managed care organizations.

A set of standards by accrediting bodies such as the Joint Commission on Accreditation of Heathcare Organizations and the National Committee on Quality Assurance will push managed care organizations in the direction of better pain management, both through market pressure and through the provision of a standard of care in tort actions. The law, after all, usually reflects the maturing and solidification of medical practice, demanding of practitioners and institutions that they measure up to standards set by their own institutions. NCQA has not yet provided specific standards for pain management, while JCAHO's new guidelines indicate that the field is maturing. NCQA should be urged to develop a standard that reinforces JCAHO's guidelines, thereby acknowledging the central importance of pain management in the care of patients.

C. Long-term care facilities: pain and quality of life

Nursing homes are increasingly the final stop before death. It has been estimated that half of the Americans who live to the age of 65 will live in a nursing home before they die.[208] In 1996, there were over 1.56 million nursing home residents in the United States.[209]

The elderly in nursing homes are often undertreated for pain.[210] Improper pain management in nursing homes can lead to high levels of chronic pain. Most nursing home residents are chronically, rather than acutely, ill. The average length of stay for nursing home patients is much longer than the average length for patients in acute-care hospitals. More than 84 percent of nursing home residents receive help with three or more activities of daily living, including eating, dressing, bathing, toileting, and transferring from one location to another.[211] Pain is often the companion for these residents.

The elderly, the primary residents of such long-term care facilities, are poorly treated. The elderly also have lacked effective tort remedies: Causation may be hard to establish, given multiple diseases, and damages are hard to prove, with the exception of pain and suffering. The primary case to date that has imposed a duty to treat for pain is *Estate of Henry James v. Hillhaven Corp.*[212]

In this case, James was admitted to a nursing home with prostate cancer that had metastasized to his left femur and spine. Upon admission, it was estimated that he had about six months more to live. His personal physician prescribed 7.5 cc's of oral morphine elixir every three hours, as needed for pain. A nurse at the nursing home countermanded this order, after assessing James as addicted. She implemented a pain management plan using a mild tranquilizer and delaying or withholding analgesics.

The court found that James experienced physical pain and suffering and mental anguish, described as "inhuman treatment" inflicted "without regard to the consequences and without care as to whether or not the patient received analgesic relief and without care that the result and procedures were torture of the human flesh."[213] During the trial, medical and nursing experts testified about the standard of care for opioid analgesics and morphine for intractable pain. A nurse also testified that proper quality assurance in nursing homes requires proper pain management.[214] Thus, the issue again becomes the role of well-established clinical practice guidelines, JCAHO accreditation standards, and other sources to which a court can turn for a standard in evaluating the failures of a physician or nurse in a long-term care setting or the failure of the facility to detect and correct negligent treatment.[215]

1. Damages and causal problems with nursing home litigation

The nursing home population, in contrast to the typical hospital patient, will have more difficulty in succeeding in private litigation to remedy harms suffered as a result of breaches of established standards of care.[216] Physical injuries such as broken bones and bruises in very frail elderly persons may be caused either by ordinary touching or by poor care or abuse. Causation, therefore, is difficult to prove. The mental impairment of many nursing home patients makes them poor witnesses, since they are unable to testify as to their experiences of pain. Their limited lifespan and their disabilities minimize legally recognizable damages for injury or death. They do not suffer lost wages. Their access to private attorneys has been limited because small damage awards discourage contingent fee arrangements and because of the isolation of institutionalization. Because of these limitations, several states have enacted statutes providing for private rights of action for nursing home residents. These statutes generally provide a cause of action for breach of statutory standards and may provide for enhanced damages and attorney's fees.[217]

2. False Claims actions under OBRA

The newest approach to poor quality of care in nursing homes is the False Claims Act under the Omnibus Reconciliation Act of 1987 (OBRA '87).[218] OBRA deals with (1) service requirements for those facilities in the Medicare and Medicaid programs; (2) a survey and certification process; and (3) enforcement and sanctions. OBRA requires a thorough assessment of each resident's functional capacity, to be used in developing a written care plan; specialized rehabilitation; a requirement that homes use less restrictive measures before turning to physical restraints; a prohibition of "unnecessary" drugs; and an explicit statutory basis for residents' rights. The goal of OBRA is to address a nursing home resident's condition so that he or she can achieve and maintain the "highest practicable physical, mental, and psychosocial well-being."[219]

The False Claims Act[220) provides a statutory source, either used by the government or in a Qui Tam action by a private party, for using OBRA as setting the minimum standard for quality of life in a nursing home. A prima

facie case need only allege that (1) the defendants presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; (3) the defendants knew the claim was false or fraudulent; and (4) the United States suffered damages as a result of the false or fraudulent claim.

The False Claims Act was initially used for overbilling or billing for unnecessary services. Its use by U.S. Attorneys against nursing homes has been based on allegations of billing for unrendered, yet necessary services, leading to a poor quality of care for residents. Providers claiming reimbursement under the federal Medicare and/or Medicaid programs implicitly certify compliance with all applicable federal regulations pertaining to program eligibility. When providers, either knowingly or recklessly, fail to render the appropriate regulated levels of care, they may be susceptible to liability under the False Claims Act, having falsely certified compliance.[221]

The False Claims Act has potential for extreme violations and obvious misconduct in nursing homes, such as bed sores and major sanitary problems with fragile elderly patients. Undertreatment of pain, absent an extreme case such as the facts in Henry James and absent an aggressive and protective family, will continue to be difficult to prove, even with this new weapon. But the specter of a large judgment based on a patient's pain is one additional source of pressure on nursing home operators to incorporate effective pain management into their care of residents.

CONCLUSION

Pain management is evolving as critics clamor for improvement in patient care. Progress, however, has been surprisingly slow -- the result of continued uncertainty by providers as to appropriate opioid use, lack of institutional attention to pain management, and inattention by medical schools.

A convergence of forces is now building pressure on health-care providers to incorporate pain management into their practices. First, JCAHO's new statement of Pain Assessment and Management establishes a new standard of pain as the "fifth vital sign," which must be monitored and treated by hospitals for continued accreditation. Second, pain management clinical practice guidelines are now readily found through the Internet for easy access by health-care providers. One can only hope that medical school education will also incorporate a contemporary version of pain management into its curriculum.

Tort liability can now build on this convergence in pain management standards. It can reflect this convergence in medical practice and amplify the message so that providers hear it and change their practices accordingly. Patients suffer from too much pain -- it is time for our hospitals, nursing homes, and doctor's offices to reduce this suffering.

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[2.] The classic article calling attention to undertreatment is that of R.M. Marks and E.J. Sachar, "Undertreatment of Medical Inpatients with Narcotic Analgesics," Annals of Internal Medicine, 78 (1973): 173.

[3.] See, for example, AMA Department of Young Physicians Services, Pain Management: Resources for Physicians (visited July 20, 2000) <http://www.texnet.net/paincare/acute.htm> (stating that "[d]espite good intentions and genuine concern for patients' comfort on the part of physicians, repeated evaluations of the state of pain therapy over the past 20 years suggest that many patients receive inadequate pain relief"); Committee on Care at the End of Life, Approaching Death: Improving Care at the End of Life, M.J. Field and C.K. Cassel, eds. (Washington, D.C.: National Academy Press, 1997): at 5. See J.J. Bonica, Effective Pain Management for Cancer Patients (St. Paul: SIMS Deltec, Inc., 1994) (eleven reports, involving nearly 2,100 patients, found that 70 percent of patients managed with opioids and other drugs have unrelieved pain until their death. See also R. Bernabel, C. Gatsonis, and V. Mor, "Management of Pain in Elderly Patients with Cancer," JAMA, 279 (1998): 1877-82 (reporting on a study of over 10,000 nursing home residents with cancer which found that, although pain is common among such residents, it is often untreated); R. Oden, "Acute Postoperative Pain: Incidence, Severity and

the Etiology of Inadequate Treatment," Anesthesiology Clinics of North America, 7 (1989): 1-15; K. Sriwatanakul, O.F. Weis, J.L. Alloza et al., "Analysis of Narcotic Usage in the Treatment of Postoperative Pain," JAM& 250 (1983): 926-29.

[4.] The term "opiophobia" refers to the unscientific and irrational fears that many people, including many health-care professionals, have about the dangers and evils of narcotics, even when prescribed to relieve pain. See A.M. Martino, "In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medial Boards Do?," Journal of Law, Medicine & Ethics, 26 (1998): 332, at 336; J.P. Morgan, "American Opiophobia: Customary Underutilization of Opioid Analgesics," in Advances in Pain Research & Therapy, vol. 11, C.S. Hill, Jr., and W.S. Fields, eds. (New York: Raven Press, 1989): 181, at 181-82.

[5.] K.M. Foley, "The `Decriminalization' of Cancer Pain," in Advances in Pain Research & Therapy, vol. 11, C.S. Hill, Jr., and W.S. Fields, eds. (New York: Raven Press, 1989): 5, at 15 (describes "rampant opiophobia" among health-care professionals and concludes that "most physicians lack sufficient knowledge of the clinical pharmacologic approaches" that would be necessary for them to assume responsibility "to manage acute and chronic pain in medical illness effectively.") See also R. Melzack, "The Tragedy of Needless Pain," Scientific American, 262 (1990): at 27.

[6.] For example, it is not true that sustained use of opioids inevitably addicts a patient; that a maximum dose for opioid use exists; or that a large dose of opioids invariably depresses respiration. See generally C.S. Hill, Jr., "When Will Adequate Pain Treatment Be the Norm?," JAMA, 274 (1995): 1881.

[7.] A.H. Lebovits, I. Florence, R. Bathina et al., "Pain Knowledge and Attitudes of Healthcare Providers: Practice Characteristic Differences," Clinical Journal of Pain, 13 (1997): 237-243 ("The overall concordant score of 56% reflects significant knowledge deficiencies regarding currently accepted principles of pain management practice, as well as beliefs that could interfere with optimal care. Perhaps even more compelling is that significant and consistent differences in knowledge and attitude exist by profession and clinical practice area." The authors found that professionals mistakenly thought that addiction to narcotics is far more prevalent in pain patients than is actually the case.) The Institute of Medicine, in a 1997 report, found that "[d]eficiencies in undergraduate, graduate, and continuing education for end-of-life care reflect a medical culture that defines death as failure and ignores care for dying people as a source of professional accomplishment and personal meaning." See Approaching Death, supra note 3, at 207.

[8.] C.S. Hill, Jr., "The Barriers to Adequate Pain Management With Opioid Analgesics," Seminars in Oncology, 20 (April 1993): 1-5.

[9.] D.E. Joranson and A.M. Gilson, "Regulatory Barriers to Pain Management," Seminars in Oncology Nursing, 14 (May 1998): 158; Hill, supra note 8; D.E. Weissman, "Doctors, Opioids, and the Law: The Effect of Controlled Substances Regulations on Cancer Pain Management," Seminars in Oncology, 20 (April 1993): 53-58.

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[11.] J.A. Paice, C. Toy, and S. Shott, "Barriers to Cancer Pain Relief: Fear of Tolerance and Addiction," Journal of Pain and Symptom Management, 16 (July 1998): 1-9.

[12.] See D.E. Hoffmann, "Pain Management and Palliative Care in the Era of Managed Care: Issues for Health Insurers," Journal of Law, Medicine &Ethics, 26 (1998): 267.

[13.] Id.

[14.] T.S. Jost, "Public Financing of Pain Management: Leaky Umbrellas and Ragged Safety Nets," Journal of Law, Medicine & Ethics, 26 (1998): 290.

[15.] A. Alpers, "Criminal Act or Palliative Care? Prosecutions Involving the Care of the Dying," Journal of Law, Medicine & Ethics, 26 (1998): 308.

[16.] K.E. Steinhauser et al., "Factors Considered Important at the End of Life by Patients, Family, Physicians, and Other Care Providers," JAMA, 284 (2000): 2476, at 2481.

[17.] See generally World Health Organization Expert Committee, Cancer Pain Relief and Palliative Care, WHO Technical Report Series, No. 804 (Geneva: World Health Organization, 1990). For earlier discussions of the problem of undertreatment, see Marks and Sachar, supra note 2, at 173-81.

[18.] Oxford Textbook of Palliative Medicine, 2nd ed., D. Doyle, G.W.C. Hanks, and N. MacDonald, eds. (Oxford: Oxford University Press, 1998): 3.

[19.] See Webster's Third New International Dictionary (1993): 1185.

[20.] See Consensus Statement from the American Academy of Pain Medicine and the American Pain Society, "The Use of Opioids in the Treatment of Chronic Pain," Clinical Journal of Pain, 13 (1997): 6.

[21.] A. Jacox et al., Management of Cancer Pain. Clinical Practice Guideline, USDHHS Pub. No. 94-0592 (Rockville, Maryland: Agency for Health Care Policy and Research, 1994).

[22.] AGS Panel on Chronic Pain in Older Persons, "The Management of Chronic Pain in Older Persons," Journal of the American Geriatrics Society, 46 (1998): 635-51, at 635. "The Guidelines describe four types of pain: (1) Nociceptive pain, ... often derived from stimulation of pain receptors. Nociceptive pain may arise from tissue inflammation, mechanical deformation, ongoing injury, or destruction. Examples include inflammatory or traumatic arthritis, myofascial pain syndromes, and ischemic disorders. Nociceptive mechanisms usually respond well to traditional approaches to pain management, including common analgesic medications and nonpharmacologic strategies. (2) Neuropathic pain results from a pathophysiologic process that involves the peripheral or central nervous system. Examples include trigeminal neuralgia, post-herpetic neuralgia, poststroke central or thalamic pain, and postamputation phantom limb pain. These pain syndromes do not respond as predictably as nociceptic pain problems to conventional analgesic therapy.... (3) Mixed or unspecified pain is often regarded as having mixed or unknown mechanisms. Examples include recurrent headaches and some vasculitic pain syndromes. Treatment of these syndromes is more unpredictable and may require various trials of different or combined approaches.... (4) Psychogenic pain results when psychological factors are judged to have a major role in the onset, severity, exacerbation, or persistence of pain.... Examples may include conversion reactions and somatoform disorders. Patients with these disorders may benefit from specific psychiatric treatments, but traditional medical interventions for analgesia are not indicated." Id. at 635-36.

[23.] Pseudoaddiction is one phenomenon that occurs throughout the population of pain patients, but is especially common among the victims of chronic nonmalignant pain. See M. Pappagallo and L.J. Heinberg, "Ethical Issues in the Management of Chronic Nonmalignant Pain," Seminars in Neurology, 17 (1997): 203, at 205. Pseudoaddiction is a range or cluster of behaviors that are suggestive of addiction, but are the iatrogenic effect of ineffective pain management.

[24.] See Joint Commission on Accreditation of Healthcare Organizations, Pain Assessment and Management: An Organizational Approach (Oakbrook Terrace, Illinois: JCAHO, 2000): 3.

[25.] D.E. Joranson et al., "Trends in Medical Use and Abuse of Opioid Analgesics," JAMA, 283 (2000): 1710, at 1710. The treatment pyramid is developed in World Health Organization, Cancer Pain Relief: With a Guide to Opioid Availability, 2nd ed. (Geneva: World Health Organization, 1996).

[26.] Id.

[27.] Id. at 1712-13 ("Opioid analgesics, including the five study drugs, are a relatively small part of drug abuse as measured by the DAWN system ... the abuse levels have remained low and relatively stable for the past seven years despite substantial increases in the medical use of opioids.... Conventional wisdom suggests that the abuse potential of Opioid analgesics is such that increases in medical use of these drugs will lead inevitably to increases in their abuse. The data from this study with respect to the opioids in the class of morphine provide no support for this hypothesis. The present trend of increasing medical use of Opioid analgesics to treat pain does not appear to be contributing to increases in the health consequences of Opioid analgesic abuse.").

[28.] See, e.g., N.I. Cherney and R. Catane, "Professional Negligence in the Management of Cancer Pain," Cancer, 76 (1995): 2181.

[29.] American Medical Association, Code of Medical Ethics (1996): 40.

[30.] American Nurses Association, Compendium of Position Statements on the Nurse's Role in End-of-Life Decisions (Washington, D.C.: American Nurses Publishing, 1992): 7 (including the Position Statement on Promotion of Comfort and Relief of Pain in Dying Patients).

[31.] A.M. Martino, "In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?," Journal of Law, Medicine & Ethics, 26 (1998): 332.

[32.] A 1995 study found that among 220 women who suffered an adverse birth outcome, such as death or serious and permanent injury to the infant, none filed a malpractice claim. F.A. Sloan and C.R. Hsieh, "Injury, Liability, and the Decision to File a Medical Malpractice Claim," Law & Society Review, 29, no. 3 (1995): 413, at 430.

[33.] D.M. Studdert, T.A. Brennan, and E.J. Thomas, "Beyond Dead Reckoning: Measures of Medical Injury Burden, Malpractice Litigation, and Alternative Compensation Models From Utah and Colorado," Indiana Law Review, 33 (2000): 1643, at 1660.

[34.] See California Medical Association and California Hospital Association: Report on the Medical Insurance Feasibility Study, D.H. Mills, ed. (San Francisco: Sutter Publications, 1977).

[35.] See generally P.A. Bell, "Legislative Intrusions into the Common Law of Medical Malpractice: Thoughts About the Deterrent Effect of Tort Liability," Syracuse Law Review, 35 (1984): 939.

[36.] A.G. Lawthers et al., "Physicians' Perceptions of the Risk of Being Sued," Journal of Health Politics, Policy & Law, 17 (1992): 463 (physicians overestimate the rate of suit for malpractice at three times the actual rate, suggesting that physicians do respond to the messages sent by litigation). See also P.C. Weiler et al., "Proposal for Medical Liability Reform," JAMA, 267 (1992): 2355, at 2356.

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[38.] Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York (Cambridge, Massachusetts: President and Fellows of Harvard College, 1990): 9-29. Physicians surveyed in the New York study felt that the malpractice threat was important in maintaining standards of care. Id. at 9-24. The report notes that "the perception of incentives largely shapes the behavior that ultimately affects patient care." Id. at 3-19.

[39.] W.B. Schwartz and D.N. Mendelson, "The Role of Physician-Owned Insurance Companies in the Detection and Deterrence of Negligence," JAMA, 262 (1989): 1342.

[40.] See WB. Schwartz and D.N. Mendelson, "Physicians Who Have Lost Their Malpractice Insurance," JAMA, 262 (1989): 1335.

[41.] Other studies have provided recent useful data on this issue. See, e.g., EA. Sloan et al., "Medical Malpractice Experience of Physicians: Predictable or Haphazard?," JAMA, 262 (1989): 3291.

[42.] N. Vidmar, Medical Malpractice and the American Jury: Confronting the Myths about Jury Incompetence, Deep Pockets, and Outrageous Damage Awards (Ann Arbor: University of Michigan Press, 1995): 265.

[43.] See Bell, supra note 35, at 973-90.

[44.] One economist has estimated "the current non-trivial incidence of injury due to negligence would be at least 10 percent higher, were it not for the incentives for injury prevention created by the one in ten incidents of malpractice that result in a claim." P. Danzon, "An Economic Analysis of the Medical Malpractice System," Behavioral Sciences & the Law, 1 (1983): 39. See also P.M. Danzon, Medical Malpractice: Theory, Evidence and Public Policy (Cambridge, Massachusetts: Harvard University Press, 1985): 10; G. Calabresi, The Costs of Accidents: A Legal and Economic Analysis (New Haven: Yale University Press, 1970); W.B. Schwartz and N.K. Komesar, "Doctors, Damages and Deterrence: An Economic View of Medical Malpractice," N. Eng. J. Med., 298 (1978): 1282; The Economics of Medical Malpractice, S. Rottenberg, ed. (Washington, D.C.: American Enterprise Institute, 1978). For a skeptical view of the signaling effect of tort litigation generally, see S.D. Sugarman, "Doing Away with Tort Law," California Law Review, 73 (1985): 555. For a critique of Sugarman's view, see H.A. Latin, "Problem-Solving Behavior and Theories of Tort Liability, California Law Review, 73 (1985): 677, at 740.

[45.] Bardessono v. Michels, 478 P. 2d 480, 484 (Cal. 1970).

[46.] Wainwright v. Leary, 623 So. 2d 233, 237 (La. Ct. App. 1993). See also Murray v. U.S., 36 F. Supp. 2d 713 (D.C.E.D. Va. 1999) (applying Virginia Law).

[47.] 466 So. 2d 856, 872-73 (Miss. 1985). Hall was followed in Turner v. Temple, 602 So. 2d 817 (Miss. 1992). 48. See, e.g., Bahr v. Harper-Grace Hospitals, 528 N.W.2d 179 (Mich. 1995).

[49.] See, e.g., Trull v. Long, 621 So. 2d 1278 (Ala. 1993). Some courts require that the plaintiff prove such a conspiracy of silence in the particular case before an instruction will be allowed. See, e.g., Thibodeaux v. Aetna Casualty & Surety Co., 216 So. 2d 314 (La. Ct. App. 1968).

[50.] See, e.g., Bates v. Meyer, 565 So. 2d 134 (Ala. 1990).

[51.] Vergara v. Doan, M.D., 593 N.E.2d 185, 187 (Ind. 1992) ("availability of facilities may be considered").

[52.] See Blair v. Eblen, 461 S.W. 2d 370 (Ky. 1970); Restatement (Second) of Torts, [sections] 299A cmt. g (1977) ("Allowance must be made also for the type of community in which the actor carries on his practice. A country doctor cannot be expected to have the equipment, facilities, experience, knowledge or opportunity to obtain it, afforded him by a large city.").

[53.] Dunning v. Kerzner, 910 F. 2d 1009 (1st Cir. 1990).

[54.] See J.H. King, Jr., "In Search of a Standard of Care for the Medical Profession -- the `Accepted Practice' Formula," Vanderbilt Law Review, 28 (1975): 1213, at 1236.

[55.] See, e.g., Toth v. Community Hospital, 292 N.Y.S.2d 440, 239 N.E.2d 368, 369 (N.Y. 1968).

[56.] See Nowatske v. Osterloh, 543 N.W. 2d 265 (Wis. 1996), where the court noted that "customary conduct is not dispositive and cannot overcome the requirement that physicians exercise ordinary care.... We recognize that in most situations there will be no significant difference between customary and reasonable practices. In most situations physicians, like other professionals, will revise their customary practices so that the care they offer reflects a due regard for advances in the profession. An emphasis on reasonable rather than customary practices, however, insures that custom will not shelter physicians who fail to adopt advances in their respective fields and who consequently fail to conform to the standard of care which both the profession and its patients have a right to expect."

[57.] Hall, 466 So. 2d at 871.

[58.] Zintek v. Perchik, 471 N.W. 2d 522, 530 (Wis. Ct. App. 1991).

[59.] See Klisch v. Meritcare Medical Group, Inc., 134 F. 3d 1356 (8th Cir. 1998), where the patient sued for negligent performance of surgery. The Court of Appeals held that (1) a jury instruction in which the jury was asked to consider the state of medical technology at time of the allegedly negligent surgery was appropriate; and (2) under Minnesota law, the jury in a medical malpractice action should weigh information available to physicians at the time of treatment and without benefit of hindsight.

[60.] See generally D. Eddy, "Clinical Policies and the Quality of Clinical Practice," N. Eng. J. Med., 307 (1982): 343.

[61.] An outpouring of writing on practice guidelines has occurred over the past several years. See generally A.J. Rosoff, "The Role of Clinical Practice Guidelines in Health Care Reform," Health Matrix, 5 (1995): 369; Committee to Advise the Public Health Service on Clinical Practice Guidelines, Institute of Medicine, Clinical Practice Guidelines: Directions for a New Program, M.J. Field and K.N. Lohr, eds. (Washington, D.C.: National Academy Press, 1990): 8; J. Ayres, "The Use and Abuse of Medical Practice Guidelines," Journal of Legal Medicine, 15 (1994): 421, at 436-38; Office of Technology Assessment, U.S. Congress, Identifying Health Technologies That Work: Searching For Evidence, OTA-H-608 (Washington, D.C.: U.S. Gov't Printing Office, 1994): 145-47; M.A. Hall and D.S. Dadakis, "Character of Guidelines Evolves, Concern Lingers Over Protection," Medical Malpractice Law &Strategy, 1.3, no. 4 (1996): 1-4.

[62.] M.R. Chassin, "Is Health Care Ready for Six Sigma Quality?," The Milbank Quarterly, 76 (1998): 565, at 574.

[63.] See, e.g., Rosoff, supra note 61, at 369.

[64.] The Agency for Health Care Policy and Research (AHCPR) within the Health Care Financing Administration, for example, has the responsibility of developing guidelines for clinical practice through the administration's Medical Treatment Effectiveness Program. This program supports research, data development, and other activities to develop and review clinically relevant guidelines, standards of quality, performance measures, and medical review criteria in order to improve the quality and effectiveness of health-care services. See Pub. L. No. 101-239 (1990).

[65.] See E.D. Kinney and M.M. Wilder, "Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities," U.C. Davis Law Review, 22 (1989): 421, at 448; J.C. West, "The Legal Implications of Medical Practice Guidelines," Journal of Health &Hospital Law, 27 (1994): 97.

[66.] Guidelines for the proper use of beta blockers are one example. See, e.g., F.P. Sarasin et al., "Successful Implementation of Guidelines for Encouraging the Use of Beta Blockers in Patients After Acute Myocardial Infarction," American Journal of Medicine, 106 (1999): 499.

[67.] See generally Kinney and Wilder, supra note 65; M.J. Mehlman, "Assuring the Quality of Medical Care: The Impact of Outcome Measurement and Practice Standards," Law, Medicine & Health Care, 18 (1990): 368.

[68.] See Roper v. Blumenfeld, 706 A.2d 1151, 1156 (N.J. Super. App. Div. 1998) (defendant allowed to use a 1992 edition of Parameters of Care for Oral and Maxillofacial Surgery: A Guide of Practice, Monitoring and Evaluation to examine his expert and cross-examine the plaintiff's expert; the textbook established that the injury suffered by the plaintiff was a known complication of the procedure).

[69.] See generally A.L. Hyams, D.W. Shapiro, and T.A. Brennan, "Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective," Journal of Health Politics, Policy & Law, 21 (1996): 289. The respectable minority defense allows a defendant physician to defend by arguing that her practice is followed by at least a respectable minority of other physicians in that practice area or specialty.

[70.] Id.

[71.] See, e.g., Miles v. Tabor, 443 N.E.2d 1302 (Mass. 1982) (obstetrician's failure to initiate resuscitation of infant immediately after delivery violated American College of Obstetricians and Gynecologists guidelines); Green v. Goldberg, 630 So. 2d 606 (Fla. Dist. Ct. App. 1993) (American College of Obstetricians and Gynecologists bulletin on breast cancer treatment used to support expert testimony); Basten v. U.S., 848 E Supp. 962 (M.D. Ala. 1994) (involving American College of Obstetricians and Gynecologists guidelines requiring that alpha-fetoprotein screening be offered and that acceptance or rejection be documented). See generally Hyams et al., supra note 69, at 296-99.

[72.] Agency for Health Care Policy and Research, Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline, AHCPR Pub. No. 92-0032 (Rockville, Maryland: U.S. Department of Health and Human Services, 1992); A. Jacox et al., Management of Cancer Pain. Clinical Practice Guideline, USDHHS Pub. No. 94-0592 (Rockville, Maryland: Agency for Health Care Policy and Research, 1994); S. Bigos et al., Acute Low Back Problems in Adults (Clinical Practice Guideline No. 14), AHCPR Pub. No. 95-0642 (Rockville, Maryland: U.S. Department of Health and Human Services, 1994).

[73.] W.S. Blau, J.A. Dalton, and C. Lindley, "Organization of Hospital-Based Acute Pain Management Programs," Hospital-Based Pain Management, 92 (1999): 465, at 466.

[74.] These guidelines can be found on-line at <http:// www.asahq.org/practice/chronic_pain/chronic_pain.html>.

[75.] J.P. Kasseri, "Patients, Physicians, and the Internet," Health Affairs, 19 (2000): 115 (noting that physicians access medical information on-line, even though older physicians are slower to adopt more wide-ranging uses for the medium).

[76.] See generally BAR. Furrow, "Broadcasting Clinical Guidelines on the Internet: Will Physicians Tune In?," American Journal of Law & Medicine, 25 (1999): 403. See, for example, LAG. Yamamoto, "Radiology Cases in Pediatric Emergency Medicine: Amplifying the Benefits of Performance

Improvement by Sharing a Hospital Performance Improvement Program with the World via the Internet," American Journal of Medical Quality, 12 (1997): 69.

[77.] The National Guideline Clearinghouse can be accessed on-line at <http://www.guideline.gov>.

[78.] The Clearinghouse was created to deal with the criticism that guidelines published in peer-reviewed medical literature do not adhere to established methodological standards. See T.M. Shaneyfelt, M.F. Mayo-Smith, and J. Rothwangl, "Are Guidelines Following Guidelines? The Methodological Quality of Clinical Practice Guidelines in the Peer-Reviewed Medical Literature," JAMA, 281 (1999): 1900.

[79.] See P.G. Shekelle and D.L. Schriger, "Evaluating the Use of the Appropriateness Method in the Agency for Health Care Policy and Research Clinical Practice Guideline Development Process," Health Services Research, 31, no. 4 (1996): 453.

[80.] "Passive dissemination of guidelines (such as via publication or the World Wide Web) is a weak way of modifying physician behavior." D.L. Schriger et al., "Implementation of Clinical Guidelines Using a Computer Charting System: Effect on the Initial Care of Health Care Workers Exposed to Body Fluids," JAMA, 278 (1997): 1585, at 1589. The studies conclude that some form of active implementation of guidelines at the local level is needed in order to involve physicians. In one study, in a hospital emergency department in a university hospital, patients were health-care workers exposed to blood. A computer charging system provided real-time information regarding history and recommendations for laboratory testing, treatment, and disposition based on rules derived from clinical guidelines. The study found that documentation and compliance improved. Compliance with testing guidelines increased from 63 percent to 83 percent during the intervention phase and decreased to 52 percent when the computer system was removed. Real-time application of a computer-based system that provides practice guidelines literally "at the physician's fingertips" may be an effective method to improve the quality of patient care. "The fusion of electronic charting, computer databases, and clinical guidelines may offer the best hope for efficiently guiding, monitoring and improving the quality of ambulatory medicine." Id. at 1590. See also I. Ray-Coquard et al., "Impact of a Clinical Guidelines Program for Breast and Colon Cancer in a French Cancer Center," JAMA, 278 (1997): 1591; K. Elam et al., "Impact of a Worker's Compensation Practice Guideline on Lumbar Spine Fusion in Washington State," Medicare Care, 35 (1997): 417 (through use of guidelines for elective lumbar fusion as part of inpatient utilization review program, tied to reimbursement limitations, lumbar fusion rate declined 26 percent compared with a 3 percent decline for all lumbar operations over five years).

[81.] See M.D. Cabana et al., "Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement," JAMA, 282 (1999): 1458.

[82.] S.D. Lande, "The Problem of Pain" (Chapter 2), in Managed Care and Pain, S.D. Lande and R.J. Kulich, eds. (Glenview, Illinois: American Pain Society, 2000): 28.

[83.] Internet-based physician-oriented Web sites are available on a commercial basis. One example is MDConsult, a commercial database available by subscription that provides easy access to hundreds of medical textbooks and treatises, as well as clinical practice guidelines. Another example is Medscape, which provides a full range of on-line resources.

[84.] See <http:#www.docucare.net/>.

[85.] See Warrick v. Giron, 290 N.W. 2d 166 (Minn. 1980).

[86.] See B.A. Rich, "The Emerging Standard of Care for Pain Management," William Mitchell Law Review, 26 (2000): 1; R.S. Shapiro, "Health Care Providers' Liability Exposure for Inappropriate Pain Management," Journal of Law, Medicine & Ethics, 24 (1996): 360 (general malpractice discussion).

[87.] State v. McAfee, 385 S.E.2d 651 (Ga. 1989), where a quadriplegic incapable of spontaneous respiration sought court approval for discontinuation of his respirator. The Georgia Supreme Court affirmed his right to refuse medical treatment and to receive proper sedation as well: "Mr. McAfee's right to be free from pain at the time the ventilator is disconnected is inseparable from his right to refuse medical treatment. The record shows that Mr. McAfee has attempted to disconnect his ventilator in the past, but has been unable to do so due to the severe pain he suffers when deprived of oxygen. His right to have a sedative (a medication that in no way causes or accelerates death) administered before the ventilator is disconnected is a part of his right to control his medical treatment." Id. at 652.

[88.] See S.H. Walzer et al., "The Physician's Responsibility Towards Hopelessly Ill Patients: A Second Look," N. Eng. J. Med., 320 (1989): 844, at 847 ("To allow a patient to experience unbearable pain or suffering is unethical medical practice."); E.D. Pellegrino, "Emerging Ethical Issues in Palliative Care," JAMA, 279 (1998): 1521, at 1521 ("not to relieve pain optimally is tantamount to moral and legal malpractice"); M. Angell, "The Quality of Mercy," N. Eng. J. Med., 306 (1982): 98, at 99 ("the treatment of severe pain in hospitalized patients is regularly and systematically inadequate.... Pain is soul destroying. No patient should have to endure intense pain unnecessarily.").

[89.] 543 N.W. 2d 265, 272 (Wis. 1996).

[90.] Shapiro, supra note 86.

[91.] 736 So. 2d 366 (C.A. La. 1999).

[92.] Most of the legal discussion of substandard practice is not found in malpractice cases, but in medical discipline actions. For example, in Holladay v. Louisiana State Board of Medical Examiners, the Louisiana State Board of Medical Examiners imposed sanctions on a physician for prescribing controlled substances in a substandard way. He had prescribed controlled drugs in the absence of any treatment plan and medical examinations for up to eight months. He had also failed to check on the substance abuse record of his patients. According to the testimony of experienced physicians, the physician had breached the standard of care for proper pain management given these omissions.

[93.] Managed Care and Pain, S.D. Lande and R.J. Kulich, eds. (Glenview, Illinois: American Pain Society, 2000): at 30.

[94.] Shapiro, supra note 86, at 361.

[95.] See Corley v. State, 749 So. 2d 926 (La. 1999); Johnson v. Kokemoor, 545 N.W. 2d 495, 508-09 (Wisc. 1996).

[96.] 713 N.E.2d 33 (1998).

[97.] 546 N.W. 495 (Wis. 1996).

[98.] 453 N.W. 2d 634 (Iowa 1990).

[99.] 385 N.W. 2d 732 (Mich. Ct. App. 1986).

[100.] Johnson v. Ruark Obstetrics and Gynecology Associates, PA., 395 S.E.2d 85 (N.C. 1990) (expectant parents of a stillborn fetus sued the physicians for the negligent infliction of mental distress, alleging that they had observed events surrounding the death of the fetus; the North Carolina Supreme Court allowed negligent infliction of emotional distress based on a test of reasonably foreseeable consequences).

[101.] See, for example, Frame v. Kothari, 515 A.2d 810 (N.J. Super. Ct. App. Div. 1985) (defendant physician's misdiagnosis of a cerebella hemorrhage and acute hydrocephalus due to blunt trauma to the skull was held to be an event perceived by the parents; first, the parents' discussion with the defendant about their son's deteriorating condition was an "observation"; and second, their distress was foreseeable after the doctor was informed of the condition and failed to properly treat it). See also Ochoa v. Superior Court of Santa Clara County, 216 Cal. Rptr. 661, 703 P. 2d 1 (Cal. 1985) (mother suffered distress after visiting her son who was receiving "woefully inadequate" medical care in a juvenile detention home).

[102.] See, for example, Smelko v. Brinton, 740 P. 2d 591 (Kan. 1987) (parents waiting outside the operating room for their baby to undergo surgery; baby is negligently burned during the surgery and they discover the burn when he is brought out; court held that merely seeing the bad result is not sufficient for recovery). But see Martinez v. Long Island Jewish Hillside Medical Center, 518 N.Y.S.2d 955, 512 N.E.2d 538 (N.Y. 1987) (physician negligently diagnosed a pregnant woman's condition as requiring an abortion; the woman aborts the fetus and then discovers the abortion was not needed; recovery allowed).

[103.] 514 S.E.2d 355 (Va. 1999).

[104.] See, e.g., Teilhaber v. Greene, 727 A.2d 518 (N.J. Super. Ct. 1999); Moore v. Baker, 989 F. 2d 1129 (11th Cir. 1993).

[105.] Case law requires physicians to warn third parties about, or take steps to protect them from, patients who are taking medication. These steps might include warning the patient about the effects of medication, or even refusing to prescribe the medication if the patient might still drive. See Welke v. Kuzilla, 375 N.W. 2d 403 (Mich. Ct. App. 1985); Myers v. Quesenberry, 193 Cal. Rptr. 733 (Cal. Ct. App. 1983) (physician failed to warn his patient, a diabetic, of the dangers of driving); Calwell v. Hassan, 908 P. 2d 184 (Kan. Ct. App. 1995) (physician treated patient for sleep disorder, failed to warn him not to drive).

[106.] Gemme v. Goldberg, 626 A.2d 318,326 (Conn. App. Ct. 1993).

[107.] See Holt v. Nelson, 523 P. 2d 211 (Wash. Ct. App. 1974).

[108.] See Morris v. Ferriss, 669 So. 2d 1316 (La. Ct. App. 4th 1996) (physician did not have to advise patient that psychiatric treatment was an alternative treatment for epileptic partial complex seizures since it was not accepted as feasible); Lienhard v. State, 431 N.W. 2d 861 (Minn. 1988) (managing pregnancy at home rather than in hospital not a choice between alternative methods of treatment; therefore, disclosure was not required).

[109.] Martin v. Richards, 531 N.W. 2d 70 (Wis. 1995) (failure to inform parents of patient that a CT scanner was available to diagnose head injuries and that facility lacked neurosurgeon to treat intracranial bleeding).

[110.] 500 N.W. 2d 691 (Wis. Ct. App. 1993).

[111.] 490 N.W. 2d 820 (Iowa 1992).

[112.] 545 N.W. 2d 495 (Wis. 1996).

[113.] Dan B. Dobbs, Law of Torts 1050 (2000).

[114.] Sears, Roebuck & Co. v. Hartley, 160 F. 2d 1019 (9th Cir. 1947).

[115.] Dobbs, supra note 113, at 1052. See also 2 Dan B. Dobbs, Law of Remedies [sections] 8.1(4) (2nd ed. 1993).

[116.] Id.

[117.] Id. at 224.

[118.] Id. at 225-226 ("most cancer pain can be managed by the appropriate assessment of the causes of pain and treatment with non-invasive opioid analgesics. However, despite recent progress in the management of cancer pain, many patients experience severe pain due to inadequate analgesia.").

[119.] American Pain Society Quality of Care Committee, "Quality Improvement Guidelines for the Treatment of Acute Pain and Cancer Pain," JAMA, 274 (1995): 1874. The Committee offered several Guidelines: First, recognize and treat pain promptly by charting patient self-reporting; commit to continuous improvement of outcome variables; and document outcomes. Second, make information about analgesics available. Third, promise patients attentive analgesic care. Fourth, define explicit policies for use of advanced analgesic technologies. Fifth, maintain a commitment to continuous improvement.

[120.] The most important work to date addressing the broad issue of medical error is the Institute of Medicine report, To Err Is Human: Building a Safer Health System. The report is groundbreaking in its emphatic recognition, finally, that health care is a complex technological system prone to error. The report calls for "a comprehensive approach to improving patient safety," noting that "[m]ost errors and safety issues go undetected and unreported both externally and within health care organizations." With the exception of anesthesia, where the recognition that systems factors cause errors has led to a fail-safe system and better training to reduce such errors, health care has yet to implement any larger mechanism to detect errors based on system deficiencies and individual errors.

[121.] S. Chandler and R. Payne, "Economics of Unrelieved Cancer Pain," American Journal of Hospice & Palliative Care, 15, no. 4 (July/August 1998): 223.

[122.] Id. at 1875.

[123.] For an early acknowledgment of this problem, see generally S.Y. Fagerhaugh and A.L. Strauss, Politics of Pain Management: Staff-Patient Interaction (Reading, Massachusetts: Addison-Wesley, 1977). A more recent review of the literature is found at Morgan, supra note 4.

[124.] C.K. Cassel, J.M. Ludden, and G.M. Moon, "Perceptions of Barriers to High-Quality Palliative Care in Hospitals," Health Affairs, 19 (2000): 166.

[125.] Acute Pain Management, supra note 72. See generally P.C. Crowley, "No Pain, No Gain? The Agency for Health Care Policy & Research's Attempt to Change Inefficient Health Care Practice of Withholding Medication from Patients in Pain," Journal of Contemporary Health Law & Policy, 10 (1993): 383.

[126.] J.A. Dalton et al., "Changing Acute Pain Management to Improve Patient Outcomes: An Educational Approach," Journal of Pain and Symptom Management, 17 (1998): 277, at 278.

[127.] B.R. Ferrell and H. Griffith, "Cost Issues Related to Pain Management: Report from the Cancer Pain Panel of the Agency for Health Care Policy and Research," Journal of Pain and Symptom Management, 9 (1994): 221, at 222 ("Development of technology for pain treatment has flourished. In essence, pain management has become a growing health-care business. The technology of patient-controlled analgesia has been adapted from postoperative use to widespread use in cancer pain management.").

[128.] E.H. Miller et al., "Institution-wide Pain Management Improvement through the Use of Evidence-Based Content, Strategies, Resources, and Outcomes," Quality Management in Health Care, 7 (1999): 28.

[129.] Blau, Dalton, and Lindley, supra note 73.

[130.] Id.

[131.] Id. at 467.

[132.] E.C. Devine et al., "AHCPR Clinical Practice Guideline on Surgical Pain Management: Adoption and Outcomes," Research in Nursing & Health, 22 (1999): 119, at 128.

[133.] Sisters of Charity of the Incarnate Word v. Gobert, 992 S.W.2d 25 (Tex. App. 1997) (negligent failure of hospital to monitor patients' room, allowing a sexual assault to occur); Lamb v. Candler General Hospital, Inc., 413 S.E.2d 720 (Ga. 1992) (hospital negligent in failing to use proper replacement parts in a medical instrument).

[134.] Washington v. Washington Hospital Center, 579 A.2d 177 (D.C. Cir. 1990) (defendant had not yet placed end-tidal carbon dioxide monitors, which allow for early detection of insufficient oxygen in time to prevent brain injury, in their operating rooms; plaintiff's injuries would have been prevented by the early detection that such monitors make possible).

[135.] See, e.g., Pearce v. Feinstein, 754 F. Supp. 308 (W.D.N.Y. 1990); Murillo v. Good Samaritan Hospital., 160 Cal. Rptr. 33 (Cal. Ct. App. 1979).

[136.] Id. at 57.

[137.] See Emory University v. Porter, 120 S.E.2d 668, 670 (Ga. Ct. App. 1961); Lauro v. Travelers Insurance Co., 261 So. 2d 261 (La. Ct. App. 1972), cert. denied, 262 So. 2d 787 (La. 1972).

[138.] Horton v. Niagara Falls Memorial Medical Center, 380 N.Y.S.2d 116 (N.Y. App. Div. 1976).

[139.] Herrington v. Hiller, 883 F. 2d 411 (5th Cir. 1989).

[140.] Air Shields, Inc. v. Spears, 590 S.W. 2d 574 (Tex. Civ. App. 1979).

[141.] Marks v. Mandel, 477 So. 2d 1036 (Fla. Dist. Ct. App. 1985).

[142.] See Habuda v. Trustees of Rex Hospital, 164 S.E.2d 17 (N.C. Ct. App. 1968) (hospital liable for inadequate rules for handling, storing, and administering medications); Herrington v. Hiller, 883 F. 2d 411 (5th Cir. 1989) (failure to provide for adequate twenty-four hour anesthesia service).

[143.] Decker v. St. Mary's Hospital, 619 N.E.2d 537 (Ill. App. Ct. 1993). Such a duty was rejected by the Maine Supreme Judicial Court in Gafner v. Down East Community Hospital, 1999 WL 605619 (Me. 1999) (refusing to recognize corporate liability action against hospitals for failing to have explicit policies in place to control the actions of independent physicians).

[144.] Fla. Stat. Ann. [sections] 768.60 (West 2001).

[145.] See, e.g., Johnson v. University of Chicago Hospital, 982 F. 2d 230 (7th Cir. 1992), on remand, 1994 WL 118192 (N.D. Ill. 1994) (holding that hospital that provided telemetry communications to ambulance paramedics, directing them to the proper hospital in the system, could be liable for negligent operation of the system).

[146.] Moser v. Heistand, 681 A.2d 1322 (Pa. 1996).

[147.] The case most identified with corporate negligence is Darling v. Charleston Community Memorial Hospital, 211 N.E.2d 253 (Ill. 1965). The Illinois Supreme Court relied upon several sources of standards to establish the standard of care for the hospital, including standards by the Joint Commission on Accreditation of Heathcare Organizations for hospital accreditation, the state licensing regulations, and the defendant's bylaws. All of these sources mandated that a hospital assume certain responsibilities for the care of the patient. The court allowed the jury to use these standards to evaluate the failure of both the nursing staff and administrators to blow the whistle on the defendant's handling of the case.

[148.] See, e.g., Williams v. St. Claire Medical Center, 657 S.W. 2d 590 (Ky. Ct. App. 1983).

[149.] See, e.g., Strubhart v. Perry Memorial Hospital Trust Authority, 903 P. 2d 263 (Okla. 1995) (adopts doctrine of independent corporate responsibility, requiring hospitals to ensure that only competent physicians have staff privileges; also requires hospitals to take reasonable steps to ensure patient safety when it knows or should know that physicians have displayed incompetence); NKC Hospitals, Inc. v. Anthony, 849 S.W. 2d 564 (Ky. Ct. App. 1993).

[150.] 591 A.2d 703 (Pa. 1991).

[151.] Such a duty was rejected by the Maine Supreme Court in Gafner v. Down East Community Hospital, 1999 WL 605-619 (Me. 1999).

[152.] Welsh v. Bulger, 698 A.2d 581 (Pa. 1997). See generally R.L. Griffith and J.M. Parker, "With Malice Toward None: The Metamorphosis of Statutory and Common Law Protections for Physicians and Hospitals in Negligent Credentialing Litigation," Texas Tech Law Review, 22 (1991): 157.

[153.] See, e.g., Cronic v. Doud, 523 N.E.2d 176 (Ill. App. Ct. 1988).

[154.] Cronic v. Doud, 523 N.E.2d 176 (Ill. App. Ct. 1988); Corleto v. Shore Memorial Hospital, 350 A.2d 534 (N.J. Super. Ct. Law Div. 1975).

[155.] Strubhart v. Perry Memorial Hospital Trust, 903 P. 2d 263 (Okla. 1995) (noting that twenty-two states have adopted some form of the corporate negligence doctrine); Albain v. Flower Hospital, 553 N.E.2d 1038 (Ohio 1990).

[156.] Oehler v. Humana Inc., 775 P. 2d 1271 (Nev. 1989).

(157.) See St. Luke's Episcopal Hospital v. Agbor, 952 S.W.2d 503 (Tex. 1997) (holding that hospitals were immune from liability under the Texas Medical Practice Act for negligent credentialing absent a showing of malice); Hull v. North Valley Hospital, 498 P. 2d 136 (Mont. 1972).

[158.] See B.R. Ferrell et al., "An Institutional Commitment to Pain Management," American Pain Society Bulletin (April/May 1994): at 16.

[159.] Decker v. St. Mary's Hospital, 619 N.E.2d 537 (Ill. App. Ct. 1993).

[160.] The new JCAHO Pain Management standards must be satisfied by hospitals, home care agencies, nursing homes, behavioral health facilities, outpatient clinics, and health plans. These standards include:

1. the right of patients to appropriate assessment and management of pain;

2. assessing the nature and intensity of pain in all patients;

3. recording the results in a way that allows regular reassessment and follow up;

4. determining and assuring staff competency in pain assessment and management, including in the orientation of all new staff;

5. establishing policies and procedures to support appropriate prescription or ordering of effective pain medications;

6. educating patients and families about effective pain management; and

7. addressing patient needs for symptom management in the discharge planning process.

These new standards will be scored for compliance in 2001. They explicitly note that pain is a co-existing condition with a number of diseases and injuries, and it requires explicit attention. For example, a patient with breast cancer should be treated effectively not only for the actual illness, but also for any associated pain.

[161.] Pain Assessment and Management, supra note 24.

[162.] This Act is also often referred to as "COBRA" for the budget reconciliation act of which it was a part, or as the "Anti-Dumping Act."

[163.] 42 U.S.C.A. [sections] 1395 dd(e)(2); Interim Final Rule with Comment Period, 59 Fed. Reg. 32,086 (1994).

[164.] The statute requires that the hospital "provide for an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition ... exists." 42 U.S.C.A. [sections] 1395 dd(a).

[165.] 42 U.S.C.A. [sections] 1395 dd(a).

[166.] But see Wey v. Evangelical Community Hospital, 833 F. Supp. 453 (M.D. Pa. 1993).

[167.] The statute defines this term as "a medical condition manifesting itself by acute: symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part." 42 U.S.C.A. [sections] 1395 dd(e)(1). This section also defines the term for women in labor.

[168.] The statute defines the terms "to stabilize" and "stabilized" with reference to the potential for material deterioration in the patient's condition, i.e., "no material deterioration of the condition is likely, within reasonable medical probability" resulting from or occurring during the transfer. 42 U.S.C.A. 1395 dd(e)(3)(A) and (B).

[169.] 42 U.S.C.A. [sections] 1395dd(c)(1).

[170.] The statute includes discharge of the patient within the definition of "transfer." 42 U.S.C.A. [sections] 1395 dd(e)(4).

[171.] 42 U.S.C.A. [sections] 1395 dd(c)(2).

[172.] 42 U.S.C.A. [sections] 1395 dd(b)(2) and (3) and (c) (1) (A) (i).

[173.] 42 U.S.C.A. [sections] 1395 dd(d)(2)(A).

[174.] 42 U.S.C.A. [sections] 1395 dd(d)(1)(A) and (B).

[175.] The statute also provides that a plaintiff in a civil action under the Act may receive "such equitable relief as is appropriate." Few reported cases thus far have issued equitable relief, but see Owens v. Nacogdoches County Hospital District, 741 F. Supp. 1269 (E.D. Tex. 1990).

[176.] 42 U.S.C.A. [sections] 1395 dd(d)(2)(A).

[177.] The statutory language requires that the patient request examination or treatment, but the request for treatment in the emergency room has generally not been the subject of dispute. However, see Stevison v. Enid Health Systems, 920 F.2d 710 (10th Cir. 1990).

[178.] 42 U.S.C.A. [sections] 1395 dd(a).

[179.] McIntyre v. Schick, 795 F. Supp. 777 (E.D. Va. 1992).

[180.] But see Collins v. DePaul Hospital, 963 F.2d 303 (10th Cir. 1992), in which the court "accept[ed] as true counsel's assertion that ordinarily" such a patient would have had a certain diagnostic procedure and that the hospital staff had thought the procedure had been done even though in fact it had not. The court upheld summary judgment for the defendant because the statute did not "require a hospital to determine ... all of the emergency medical conditions from which a particular individual may be suffering." The applicability of this statement should be limited to the facts of Collins: the patient was transported to the emergency room with multiple injuries, including a fractured skull, and he stayed at the hospital for nearly a month recovering from his injuries. A fractured hip was not detected.

[181.] See, e.g., Baber v. Hospital Corporation of America, 977 F.2d 872 (4th Cir. 1992); Cleland v. Bronson Health Care Group, 917 F.2d 266 (6th Cir. 1990).

[182.] See, e.g., Cleland v. Bronson Health Care Group, 917 F.2d 266 (6th Cir. 1990); Baber v. Hospital Corporation of America, 977 F.2d 872 (4th Cir. 1992); Deberry v. Sherman Hospital Association, 769 F. Supp. 1030 (N.D. Ill. 1991); Urban v. King, 834 F Supp. 1328 (D. Kan. 1993).

[183.] See Abercrombie v. Osteopathic Hospital Founders Association, 950 F.2d 676 (10th Cir. 1991), for jury instructions on liability for violation of each of the requirements of the Act.

[184.] See, e.g., Collins v. DePaul Hospital, 963 F.2d 303 (10th Cir. 1992); Thornton v. Southwest Detroit Hospital, 895 F.2d 1131 (6th Cir. 1990).

[185.] See, e.g., Burditt v. United States, 934 F.2d 1362 (5th Cir. 1991); Delaney v. Cade, 986 F.2d 387 (10th Cir. 1993); Green v. Touro Infirmary, 992 F.2d 537 (5th Cir. 1993).

[186.] 42 U.S.C.A. [sections] 1395(e)(3)(A) (emphasis added).

[187.] See generally Hoffmann, supra note 12.

[188.] According to clinical practice guidelines on the management of chronic pain in older persons, "[f]or some conditions, chronic pain is defined as pain that exists beyond an expected time frame for healing. For other conditions, it is well recognized that healing may never occur. In many cases, chronic pain is understood as persistent pain that is not amenable to routine pain control methods. Because there are many differences in what may be regarded as chronic pain, the definition remains flexible and related to specific diagnoses or cases." AGS Panel on Chronic Pain in Older Persons, supra note 22 and accompanying text on the four types of pain, at 635-36.

[189.] See M. Caudill et al., "Decreased Clinic Use by Chronic Pain Patients: Response to Behavioral Medicine Intervention," Clinical Journal on Pain, 7 (1991): 305-10.

[190.] S.M. Wolf, "Physician-Assisted Suicide in the Context of Managed Care," Duquesne Law Review, 35 (1996): at 471.

[191.] See R.N. Jamison, "Comprehensive Pretreatment and Outcome Assessment for Chronic Opioid Therapy in Nonmalignant Pain," Journal of Pain and Symptom Management, 11 (1996): at 231 ("no empirical studies have been conducted to substantiate these guidelines"); accord D. Justins, Book Review, "Pain Medicine: A Comprehensive Review" (Book Review), Lancet, 347 (1996): 814.

[192.] Herrara v. Lovelace Health Systems, Inc., 35 F. Supp. 2d 1327 (D.C.N.M. 1999); Hoose v. Jefferson Home Health Care, Inc., 1998 WL 114492 (E.D. Pa 1998) (with claims of vicarious liability and negligence in post-operative care, selection of therapists, and overall supervision of care, the court noted that "this case is nothing more than a medical malpractice case" and refused to uphold ERISA preemption).

[193.] Harris v. Deaconess Health Services Corp., No. 4:99-CV701 CAS (E.D. Mo. 1999); Herrera v. Lovelace Health System, Inc., 35 F. Supp. 2d 1327 (D.N.M. 1999); Visconti v. U.S. Healthcare, 1998 WL 968473 (E.D. Pa. 1998); Petrovich v. Share Health Plan of Illinois, Inc., 1999 WL 773524 (Ill. 1999); Dykema v. King, 959 F. Supp. 736 (D.S.C. 1997); Prihodav. Shpritz, 914 F. Supp. 113 (D.C. Maryland 1996); Pacificare of Oklahoma, Inc. v. Burrage, 59 F.3d 151 (10th Cir. 1995); Lupo v. Human Affairs Int'l, Inc., 28 F.3d 269 (2d Cir. 1994); Dearmas v. Av-Med, Inc., 865 F. Supp. 816 (S.D. Fla. 1994); Gilbert v. Sycamore Municipal Hospital, 622 N.E.2d 788 (Ill. 1993).

[194.] Eaccarino v. Canlas, 1998 WL 195875 (E.D. Pa. 1998) (agency theory is a "garden variety" tort not preempted by ERISA).

[195.] See Rice v. Panchal, 65 F.3d 637 (7th Cir. 1995).

[196.] Jass v. Prudential Health Care Plan, Inc., 88 F.3d 1482 (7th Cir. 1996).

[197.] See McDonald v. Damian, 1999 WL 500133 (E.D. Pa. 1999) (claim for inadequacies in the delivery of medical services).

[198.] Pappas v. Asbel, 724 A.2d 889, 893 (Pa. 1999).

[199.] Shannon v. McNulty, 718 A.2d 828 (Pa. Super. Ct. 1998)

[200.] 4 F. Supp. 2d 888 (D.C. Ariz. 1998).

[201.]Id. at 893.

[202.] Hoyt v. Edge, 1997 WL 356324 (E.D. Pa. 1997).

[203.] Miller v. Riddle Memorial Hospital, 1998 WL 272167 (E.D. Pa. 1998).

[204.] Snow v. Burden, 1999 WL 387196 (E.D. Pa. 1999).

[205.] Newton v. Tavani, 962 F. Supp. 45 (D.C.N.J. 1997).

[206.] 120 S. Ct. 2143 (2000).

[207.] Hoffmann, supra note 12, at 283-284

[208.] J. Zerzan, S. Stearns, and L. Hanson, "Access to Palliative Care and Hospice in Nursing Homes," JAMA, 284 (2000): 2489, at 2489.

[209.] N.A. Krauss and B.M. Altman, "Characteristics of Nursing Home Residents -- 1996," (visited February 28, 2001) <http://www.meps.ahrq.gov/papers/99-0006/99-0006.htm>.

[210.] Id. at 2490. See also B.A. Ferrell et al., "Pain in the Nursing Home," Journal of the American Geriatrics Society, 38 (1990): 409; P.R. Mobily et al., "An Epidemiological Analysis of Pain in the Elderly: The Iowa 65 + Rural Health Study," Journal of Aging & Health, 6 (1994): 139.

[211.] Hoffmann, supra note 12, at 283.

[212.] Super. Ct. Div. No. 89-CVS64, Hertford County, N.C. (Nov. 20, 1990) (cited in Shapiro, supra note 86, at 361).

[213.] R. Angarola, "Inappropriate Pain Management Results in High Jury Award" (Letter), Journal of Pain & Symptom Management, 6 (1991): 407.

[214.] D.Q. Haney, "Control of Pain Gains Priority in Cancer Treatment Centers; Medicine: More and More Doctors are Paying Attention to Patients' Discomfort," L.A. Times, March 15, 1992, at A-1 (noting that patient's family was awarded $15 million from the nursing home).

[215.] In Bergman v. Chin, the family of an elderly hospital patient filed suit after the state medical board failed to act against the treating physician. The daughter said: "We found that the care was grossly inadequate to my father, that they did not provide adequate pain medication or relief to him while he was in the hospital or when he was discharged to our home to have hospice care." California's Elder Abuse Act has no cap like that for medical malpractice claims. Punitive damages and attorneys fees are recovered, and pain and suffering survives death and can accrue to the estate. "The goal of the family in this case and of Compassion in Dying is that this kind of accountability will motivate physicians and other providers to be more attentive and aggressive in caring for pain." V. Foubister, "Doctor Faces Charges for Allegedly Undertreating Pain," AMA News (March 20, 2000).

[216.] J.B. Stern, "Malpractice in the Managed Care Industry," Creighton Law Review, 24 (1991): 1285; J.P. Ludington, Licensing and Regulation of Nursing or Rest Homes, 53 A.L.R.4th 689 (1993); L.B. Frantz, Patient Tort Liability of Rest, Convalescent, or Nursing Homes, 83 A.L.R.3d 871, 875 (1993) (discussing the general standard of care for nursing homes as the "degree of care, skill, and diligence used by such homes generally in the community"); Stogsdill v. Manor Convalescent Home, Inc., 343 N.E.2d 589 (Ill. App. Ct. 1976) (holding that usual or customary care did not necessarily preclude a finding of negligence). See M.B. Kapp, "Malpractice Liability in Long-Term Care: A Changing Environment," Creighton Law Review, 24 (1991): 1235; M.B. Kapp, "Nursing Home Restraints and Legal Liability: Merging the Standard of Care and Industry Practice," Journal of Legal Medicine, 13 (1992): 1.

[217.] See, e.g., Stiffelman v. Abrams, 655 S.W.2d 522 (Mo. 1983) and Harris v. Manor Healthcare Corp., 489 N.E.2d 1374 (Ill. 1986), both interpreting state statutes creating private rights of action. See also Stewart v. Bernstein, 769 F. 2d 1088 (5th Cir. 1985); Chalfin v. Beverly Enterprises, 741 F. Supp. 1162 (E.D. Pa. 1989), holding no private right of action under "pre-OBRA 1987" federal statutes. But see Roberson v. Wood, 464 F. Supp. 983 (E.D. Ill.

1979), holding that a private right of action existed. Despite these earlier cases, one could argue that there is an implied private right of action under the current federal statute. The Medicaid and Medicare statutes provide that the statutory remedies "are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law." 42 U.S.C.A. [sections] 1395i-3(h)(5); 42 U.S.C.A. [sections] 1396r(h)(8). Legislative history indicates some support for a Congressional intent to allow a private right of action on the part of nursing home residents. The House Energy and Commerce Committee explained the intent of the above provision by stating that it would include "private rights of action to enforce compliance with requirements for nursing facilities." H.R. Rep. No. 391(I), 100th Cong., 1st Sess. 472. See Martin v. Voinovich, 840 F. Supp. 1175 (S.D. Ohio 1993), holding that there is a private right of action under the OBRA provisions, enforceable through 42 U.S.C.A. [sections] 1983. Residents may also have a statutory right to initiate sanctions. See, e.g., 210 Ill. Comp. Stat. 45/3-503, allowing residents to petition for receivership; Kizer v. County of San Mateo, 279 Cal. Rptr. 318,806 P. 2d 1353 (Cal. 1991), discussing right of private party to bring an action if the agency does not assess a fine.

[218.] OBRA '87, 42 U.S.C. [sections] 1396r (involving the enhancement of quality of life and the psychosocial needs of residents).

[219.] 42 U.S.C. [subsections] 1395i-3(a)-(h), 1396r(a)-(h) (1988). See generally TS. Edelman, "The Nursing Home Reform Law: Issues for Litigation, 24 Clearinghouse Rev. 545, at 545-49 (1990).

[220.] 31 U.S.C.A. [subsections] 3729-33.

[221.] See M. DuBois Krohn, "The False Claims Act and Managed Care: Blowing the Whistle on Underutilization" (Comment), Cumberland Law Review, 28 (1998): 443, at 458.

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Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards

Diane E. Hoffmann and Anita J. Tarzian

Uncertainty regarding potential disciplinary action may give physicians pause when considering whether to accept a chronic pain patient or how to treat a patient who may require long-term or high doses of opioids. Surveys have shown that physicians fear potential disciplinary action for prescribing controlled substances and that physicians will, in some cases, inadequately prescribe opioids due to fear of regulatory scrutiny. Prescribing opioids for long-term pain management, particularly noncancer pain management, has been controversial; and boards have investigated and, in some cases, disciplined physicians for such prescribing. While in virtually all of these cases the disciplinary actions were successfully appealed, news of the success was not often as well-publicized as news of the disciplinary actions, leaving some physicians confused about their potential liability when prescribing opioids for pain. The confusion has perhaps increased as a result of two relatively recent cases, one where a physician was successfully disciplined by a state medical board for undertreatment of his patients' pain, and another where the physician was successfully sued for inadequate pain treatment.

In the first case, in September 1999, the Oregon Medical Board disciplined a physician for failure to adequately treat several of his patients for pain. Less than two years later, a California physician was successfully sued for his undertreatment of a patient's pain. These cases reflect a changing attitude toward pain treatment in the United States — a recognition that patients, especially patients at the end of life, have a right to adequate pain treatment. This shift in thinking appears to have begun in the late 1980s. Prior to this time, "according to established medical opinion, the likelihood of addiction to opioids was considered too great to prescribe them to any patients but those suffering from the most serious pain."[1] This opinion was conveyed by a number of state medical boards to physicians who were disciplined for prescribing outside of these boundaries. The "sea change" came about "as evidence mounted that patients, especially cancer patients, were being undertreated for their pain, and that addiction was not a significant problem for pain patients with no prior history of substance abuse."[2] In response, physicians began to prescribe greater amounts of pain medication. In addition, professional and governmental agencies established clinical guidelines encouraging the appropriate use of opioids in the treatment of cancer pain. Many state legislatures also passed "intractable pain statutes." These laws "were designed to provide physicians with some assurances by reducing both the real and perceived risks of being subjected to regulatory sanctions for treating pain with controlled substances."[3]

Yet, at the same time that these new legal pressures would seem to counteract the pressures to undertreat, a renewed concern about drug diversion, in light of the abuse associated with OxyContin, has taken shape. Evidence of diversion of the medication from legitimate users to addicts has caught the attention of drug and law enforcement agencies that have linked OxyContin to overdose deaths, pharmacy robberies, and other criminal activities related to obtaining the drug. This turn of events has the potential for rekindling the attention of state medical boards and law enforcement agencies toward physician prescribing practices for patients suffering from pain.

In an effort to better understand how state medical boards are evaluating and balancing the need for adequate pain treatment with concerns about drug diversion and inappropriate prescribing, we undertook a survey of state medical boards across the country. This article, after briefly describing the evolution of medical knowledge regarding the treatment of

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pain, the history of efforts to regulate controlled substances used to treat pain, and the literature regarding physician concerns about legal repercussions for prescribing opioids, reports on the results of the survey.

We conclude that boards have made improvements in the way they approach physicians who prescribe large doses of opioids. Greater reliance on pain policies has given many boards clearer criteria for when to investigate and discipline physicians for opioid prescribing violations. The observed improvements involve recognition by most boards that physicians have an obligation to provide adequate pain management to their patients. This recognition has required boards to balance their concerns about opioid overprescribing with their concerns about pain undertreatment. We found, however, that boards appear to be more concerned with violation of standard of care in cases of overtreatment versus undertreatment. Respondents (speaking on behalf of their boards) viewed opioid overprescribing as a clear violation of standard of care *and* a clear example of patient harm, whereas pain undertreatment — particularly for nonmalignant chronic pain — was not so clearly perceived as a standard of care violation, and generally required a higher threshold of harm. We conclude that the boards are still trying to find the right balance between promoting adequate pain management and protecting against opioid diversion and abuse.

The Evolution of Treating Pain with Opioids

Progress in pain management has evolved over the last few decades. Beginning with the hospice movement in the 1960s, and continuing beyond the 1994 guidelines for the management of cancer pain published by the Agency for Health Care Policy & Research, opioids (in combination with other medications) have been identified as the standard treatment for moderate to severe cancer pain. In addition, opioid therapy has been shown to be effective for patients with certain types of chronic nonmalignant pain, without the occurrence of intolerable side-effects or the development of aberrant drug-related behaviors.[4] Its use in patients with malignant and nonmalignant pain has been shown to improve functional status and quality of life.[5] Moreover, the consensus among addiction specialists is that substance abuse history per se does not preclude the use of opioids for pain management, but it does mandate careful assessment and monitoring of such patients by a trained pain specialist.[6]

At the same time that these pain management treatment standards have evolved, there have been ongoing efforts to regulate the prescribing of opioids. These efforts began with the passage in 1970 of the Controlled Substances Act and the establishment in 1973 of the Drug Enforcement Agency (DEA). At the federal level, the Controlled Substances Act and the DEA make up the main armaments in the government's efforts to prevent drug abuse. At the state level, there are comparable laws as well as state drug enforcement agencies and bureaus of narcotics control. Since the 1970s, the government's attitude has shifted in focus, particularly after President Reagan took office, from viewing drug abuse as a public health problem to viewing it as a political, law enforcement, and moral issue.[7] Although the DEA and other federal laws and policies tend to be less restrictive of physician practices than state laws and enforcement practices, concerns about Medicare and Medicaid fraud and abuse and the government's "war on drugs" have put pressure on state medical boards.[8] This has resulted in some state boards disciplining physicians for "overprescribing" opioids, including physicians who were treating pain patients.[9] Thus, in addition to fears that patients will become addicted,[10] and that doses of opioids that are too high will lead to patient deaths,[11] physicians avoid prescribing opioids because they believe they may face legal or regulatory sanctions or simply be the target of investigation by licensing boards or other law enforcement agencies.[12] However, research has shown that physicians' fears of legal or regulatory sanctions are more the result of a "chilling effect" than of the actual risk of disciplinary or legal liability they face if they properly prescribe opioids for pain management.[13]

Several physician surveys have provided evidence of the chilling effect of sanctions against physicians for opioid prescribing. In 1990, physician members of the Eastern Cooperative Oncology Group were surveyed and 18 percent of 897 responding oncologists rated excessive regulation of analgesics as one of the top four barriers to adequate cancer pain management.[14] In a 1991 survey of members of the American Pain Society, 40 percent of surveyed physician members said concerns about regulatory scrutiny rather than medical reasons led them to avoid prescribing opioids for chronic noncancer pain patients.[15] In a survey of Wisconsin physicians conducted in the same year, over half reported decreasing the dose, quantity, or number of refills, or switching to a lower scheduled medication, due to fear of regulatory scrutiny.[16] And, in a 1993 California survey, 69 percent of physician respondents felt that doctors were more conservative in their use of opioids in pain management because of fear of disciplinary action, and a third felt that their own patients may be suffering from untreated pain.[17]

In an effort to better understand state medical board members' knowledge and attitudes toward physician prescribing of opioids for pain management, the University of Wisconsin Pain & Policy Studies Group (PPSG) conducted a survey of members of state medical boards in 1991. Joranson and colleagues found that "[w]hile most respondents agreed that the prescribing of opioids for the cancer patient was legal and generally acceptable medical practice, only 12% were confident in the legality of prescribing for the patient with chronic non-cancer pain; the majority of respondents (77%) would discourage this practice or even investigate it as a violation of the law."[18] They also found that board members responding to the survey had a lack of knowledge about

cancer pain management and the meaning and incidence of addiction when opioids are used to manage pain. In 1997, the PPSG (which conducted workshops between 1994 and 1998 to educate board members around the country about pain management issues) repeated the survey and found some improvements in attitudes of medical board members. Specifically:

- respondents were more likely in 1997 than in 1991 to recognize that opioids are underutilized as analgesics for cancer pain;
- respondents in both surveys overestimated the incidence of addiction to pain medications, but in 1997 fewer respondents confused addiction with physical dependence; and
- medical board members in 1991 and 1997 were more skeptical about prescribing opioids for noncancer than for cancer pain, but respondents in 1997 were more likely to consider prescribing opioids to patients with chronic noncancer pain for more than several months as acceptable medical practice.[19]

Since 1997 there have been a number of changes in the legal landscape regarding the prescribing of opioids for pain. Recently there has been an increased focus on undertreatment of pain, influenced in part by the increased attention given to palliative and end-of-life care and the controversy surrounding physician-assisted suicide. The American Society of Law, Medicine & Ethics (ASLME), with support from the Mayday Fund,[20] has addressed the issue of pain undertreatment through a variety of educational initiatives and projects. In 1998, ASLME's joint work with the Federation of State Medical Boards (FSMB) resulted in 1998 in the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, thus giving clear guidance to state medical boards regarding opioid use for chronic pain.[21] The PPSG has been tracking the adoption of the Model Guidelines as well as other state pain policies more generally for over a decade. From 1989 to 2001, there was a dramatic increase in the number of new state pain policies adopted by state boards and legislatures. Many state boards have adopted policies that are consistent with the FSMB's Model Guidelines (e.g., endorsement of a balance between preventing opioid misuse and not interfering with appropriate opioid prescribing; endorsement of multidisciplinary collaboration in treating pain patients; inclusion of treatment standards for chronic nonmalignant pain as well as standards for acute and cancer-related pain).[22] However, there is no literature indicating how state boards are applying the guidelines and whether they are *implementing* balanced policies for the management of both malignant and nonmalignant pain.

In addition to the efforts of the ASLME, PPSG, and FSMB, groups like Compassion in Dying have been trying to counter the chilling effect of sanctions for opioid prescribing by drawing attention to cases in which pain was undertreated. In 1999, the Oregon Medical Board was the first in the nation to discipline a physician for failure to prescribe adequate pain relief medication. The physician, Dr. Paul Bilder, was cited for several pain undertreatment infractions, including prescribing insufficient pain medication for a terminally ill cancer patient (i.e., only Tylenol) and prescribing only a fraction of the dose of morphine that another patient needed and the hospice nurse suggested. Dr. Bilder was ordered by the medical board to complete an educational program on physician-patient communication and undergo mental health treatment.[23] In another case, in June 2001, a California jury awarded 1.5 million dollars to the surviving children of William Bergman, whose children sued their father's physician, Dr. Wing Chin, for undertreating Mr. Bergman's cancer pain before he died. Although the award was subsequently reduced by the court, it was a dramatic message to physicians. Moreover, in the same year, drug enforcement officials from the DEA and twenty-one health organizations issued a joint statement that they had begun to work together "to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need."[24]

Almost at the same time that we experienced this shift in focus toward concerns about undertreatment of pain, a new risk surfaced that threatens the balance of providing effective pain relief while minimizing abuse and diversion of opioids—the abuse of OxyContin. OxyContin was approved by the Food and Drug Administration in 1995. It has fewer side-effects than morphine but works similarly. It contains oxycodone in a time-released formulation that works over 12 hours, making it ideal for sufferers of both malignant and nonmalignant chronic pain. However, abuse of the drug began when it was discovered that crushing the tablet and either snorting it or mixing it with water and injecting it produced a potent high. Thus, OxyContin has high addictive potential for drug abusers and a high street value. According to the DEA Office of Diversion Control, from 1996 to 1999 the number of drug abuse deaths reported to the Drug Abuse Warning Network (DAWN) that involved oxycodone more than quadrupled, with 268 deaths in 1999 compared to 51 in 1996.[25] Several cases were reported in the media stating that physicians who prescribed OxyContin in relatively high doses were disciplined by their state medical boards.[26]

Survey of State Medical Boards

In order to better understand how state medical boards are balancing concerns about physicians undertreating pain with concerns about physicians overprescribing opioids, we undertook a nationwide survey of state medical boards. More specifically, the study sought information regarding trends in the number and nature of complaints received by boards for inappropriate prescribing of opioids (i.e., "overprescribing" or "underprescribing"), how boards evaluate such complaints, and under what circumstances boards would discipline phy-

sicians falling into one of those categories. The focus of the survey was board experience during the last 5 years (1997–2001). The survey was conducted in late 2001 and the first half of 2002, just after the high visibility given to the abuse of OxyContin in the press.

Methods

As a first step, we developed a telephone survey tool based on available literature and input from experts in the field of pain research and state medical board staff to identify state medical board practices related to prescribing of opioids for the treatment of pain.[27] Survey questions included the nature of complaints the board received over the previous 5 years regarding opioid overprescribing and subsequent investigations of physicians and disciplinary action taken; the nature of complaints the board received regarding undertreatment of pain by a physician; the board's use of a pain management expert in cases involving opioid prescribing; the likelihood of the board taking disciplinary action against a physician for undertreatment of pain; and the board's educational activities directed to physicians regarding treatment of patients with pain. The study was approved by a University of Maryland institutional review board.

The survey was directed (by name) to the state board medical director, or individual with a comparable title, and that individual was asked to participate in the survey or to provide the name of someone else in the agency who would be most able to answer the survey questions. Of the fifty states and the District of Columbia, thirty-eight state medical boards participated (a 74.5 percent response rate). Seventeen respondents were state medical board directors, ten were chief investigators or prosecutors, and the remaining eleven included individuals with the following titles: "medical director," "medical consultant," "program administrator," "senior complaint analyst," "chief [or 'director'] of compliance," "consumer assistant," and "director of complaints and allegations." The respondents' average number of years in their current position was 6.0 (standard deviation = 5.7). Ten respondents were physicians, seven were lawyers, three were nurses, two were social workers, and several had other advanced degrees (e.g., in business, public administration, and public health). Ten had worked in a similar capacity before working in their current position. Thirty-four respondents completed the survey by phone, and four completed the survey in written form.[28] Qualitative comments were transcribed directly from phone conversations or from written comments on faxed or mailed-in surveys.

Boards of those who responded differed in two significant respects from those who did not. First, respondents were more likely not to have regulations, guidelines, statutes, or policies regarding opioid prescribing than nonrespondents. Interestingly, all of the boards without such regulations, guidelines, statutes, or policies participated.[29] Second, respondents were more likely than nonrespondents to have implemented an electronic prescription monitoring program that provides access to a database of physicians' prescribing and pharmacists' dispensing practices from pharmacies in the state. A total of sixteen states have currently implemented a prescription monitoring program, all of which are electronic.[30] Thirteen of those sixteen states responded to the survey.

Results

Opioid overprescribing: Complaints

Respondents were asked to estimate the number of complaints[31] their board had received in 2001 related to opioid overprescribing (i.e., "physicians who allegedly prescribed opioids unnecessarily, in too high a dose, or for too long a duration").[32] An estimate was requested because most boards do not formally categorize complaints that relate specifically to opioid overprescribing.[33]

Twenty-five respondents were able to estimate the number of opioid overprescribing complaints in 2001. According to those estimates, the average number of complaints was 3.1 per 1,000 doctors in the state (standard deviation = 2.8, range = 0 to 13.8).[34] The most common sources of these complaints were pharmacies, government regulatory agencies such as the DEA, and family members of patients. Other sources included physicians, law enforcement agents, or the board itself (i.e., in the course of another investigation, the board may have discovered cases of suspected opioid overprescribing). Some qualifying comments regarding the number of complaints included: "some [complaints] run together, for example, a complaint about sexual involvement may overlap with [a complaint about] opioid overprescribing," and "we do not track it that way, but my sense is, it's extremely small. Out of 700 complaints ... under a dozen tend to be related to [opioid overprescribing, mostly criminal referral]."

Eleven respondents were not able to estimate the number of opioid overprescribing complaints their board received in 2001 and shared comments such as: "we don't keep that type of information.... [W]e categorize drug diversion, incompetence, negligence.... I really don't know"; "I know the number of complaints for inappropriate prescribing, but I don't know how many of those were for opioid overprescribing"; and "I couldn't give a fair estimate, we have codes within our tracking system, but a lot of time the tracking code we put in isn't the same as the order to show cause or the final adjudication." In this regard, one respondent reported that his board was "getting ready to add undertreatment of pain to the [complaint form] as a specific cause."

When respondents were asked their impression of whether complaints against physicians for opioid overprescribing had increased, decreased, or stayed the same in the

Table 1. Perceived Trends in Complaints, Investigations, and Disciplinary Actions for Overprescribing Opioids from 1997–2001.

	Increased	Decreased	Stayed the Same	No Opinion
Complaints	14 (37%)	4 (10.5%)	17 (44.5%)	3 (8%)
Investigations	15 (39.5%)	3 (8%)	17 (44.5%)	3 (8%)
Disciplinary Actions	14 (37%)	6 (16%)	15 (39.5%)	3 (8%)

past 5 years, seventeen respondents (44.5 percent) thought complaints had stayed the same ("on average there's a relatively fixed population of drug-seeking patients and a relatively constant population of providers willing to prescribe"), fourteen (37 percent) thought they had increased, four (10.5 percent) thought they had decreased, and three did not know (see Table 1).

Drug diversion and abuse trends: OxyContin

Respondents were asked whether the problem of drug diversion and abuse in their state, in general, had improved, become worse, or stayed the same in the last 5 years. Eighteen (47 percent) thought it had become worse, eleven (29 percent) thought it had stayed the same, and five (13 percent) thought it had improved. Four had no real impression. Some commented that the drug diversion/abuse problem was not necessarily worse, but the board was doing more ("taking a little sterner approach than before 1996"; "pursuing it more diligently; we're more on top of it now"; and "we have more sophisticated investigatory techniques, so we may just be more aware of what's going on"). Fifteen of the eighteen who thought drug diversion and abuse in their state had become worse (83 percent) thought that the abuse and diversion of OxyContin had contributed to that trend, while the remaining three thought it had not. Some identified the problems with OxyContin as prompting newly enacted legislation establishing a prescription monitoring program in the state. One respondent commented:

> Any time you have a drug that has as much press as [OxyContin], it identifies weaknesses in systems. Then you have people who are more willing to look for new ways to identify diversion and abuse. This might be one aspect that plays into the desire of some to have this new drug monitoring system … [to find] mechanisms to identify if a patient had been to other physicians [looking for drugs to feed an addiction], or indications of [drug] diversion/abuse, for peace of mind of the physician.

Another stated: "an electronic database system would be ideal. It works both ways: If a doctor wonders if he's the sixth doc in the pathway, he can call the board and get the answer in a few minutes, and [vice versa]."

Some respondents thought the abuse of OxyContin had made the public more aware of diversion issues, but had "not increased [their] complaints or investigations." Others made reference to OxyContin's being "the drug of the month" ("20 years ago it was Dilaudid, then Percocet, once upon a time it was Demerol"; "OxyContin is a new problem, but Lortab is more abused; there's still a diverse array of drugs"; "OxyContin is just another drug in the mix"). One respondent commented: "we don't have issues with physicians abusing OxyContin.… [O]ur problem has been with patients selling or diverting the OxyContin and physicians not tuning in to that." A few respondents, however, described serious problems in their state with overdose deaths from OxyContin, or of people in their state breaking into pharmacies and holding pharmacists up at gunpoint, specifically requesting OxyContin ("we have seen a tremendous problem of criminal theft of OxyContin"). One respondent described local police and health care providers with an "otherwise unblemished record for 20 years … getting addicted to OxyContin … [and] stealing from patients." Others reported increased prescriptions of OxyContin, but as one respondent commented: "that's not proof of diversion."

Investigations for overprescribing

When asked whether their board had changed its approach to investigating physicians for opioid prescribing in response to OxyContin abuse and diversion, twenty-nine (76 percent) said no and five (13 percent) said yes. Four had no opinion. Those who had not changed their approach commented that they conducted the "same thorough investigation" of all valid complaints. Others felt their investigative approach had not changed, but their attention to the issue had increased. One respondent identified drug diversion as a priority of the board, which was working more with law enforcement to "stay on top of what's going on." Another respondent explained that

the approach of their board included adapting to changes in drug-seeking and diversion behaviors over the years:

> [The] physician's committee of the medical society ... offers very consistent counsel; they've tightened their procedures over the years because the screening tests we had in place for monitoring [opioids] needed to be beefed up. They found loopholes like ... "beat-the-piss-test.com" websites, [which led to requiring] all testing at one lab. We've gone back and identified a lot of problems. It's better to nip it in the bud before it gets too out of control.

Another respondent commented:

> It's just a change in the marketplace we've taken cognizance of. We just had a huge case of overprescribing where in the testimony it became apparent the number of patients looking for this kind of prescriber. This particular doc had people coming from other states. That was his defense: "If someone is in pain, you give them drugs." But the board said, "Not necessarily. You comply with good medical practice; you assess them and follow up and keep records, etc. You don't just give them drugs."

Respondents from other boards admitted that finding the right balance between identifying physicians who overprescribe opioids and those who are appropriately treating chronic pain is not always easy. As one respondent stated: "[We're] still working on trying to figure out the appropriate balance between pain management and overprescribing. We're still looking at research to find that balance."

When asked whether board investigations of physicians' opioid prescribing practices had increased, decreased, or stayed the same over the past 5 years (1997–2001), seventeen respondents (44.5 percent) said the number of investigations had stayed the same, fifteen (39.5 percent) said they had increased, three (8 percent) said they had decreased, and three did not know (see Table 1). Respondents were asked why they thought the number of investigations had increased or decreased. For those that answered increased, the most commonly cited reasons were increased "public awareness.... patients and families are more aware," and "people are more inclined to speak up than they have been in the past." Some mentioned law enforcement actions ("there have been more cases where there have been convictions [of physicians] on drug trafficking and selling [opioid] prescriptions for money").

For those that answered decreased, one respondent cited economic factors that limited the resources the board could direct toward investigations. Changes in the board's attitude toward opioid prescribing was mentioned as a reason for increased *and* decreased investigations over the past 5 years. One respondent shared his impression that "the board is taking these cases more seriously than in the past ... [by] cracking down on doctors who are overprescribing, and wanting us to find information to back that up." Another mentioned that physicians have clearer grounds for being investigated if they do not understand the board's rules for the treatment of chronic pain and are practicing outside of their specialty area. Others pointed to their board's changed attitude toward the treatment of chronic pain and how this has resulted in fewer full investigations: "The board's attitude toward prescribing opioids has changed. If a doctor can provide documentation showing that [s]he's following pain management guidelines, the board doesn't pursue [it] further."

Respondents were asked what factors would determine whether their board would fully investigate a physician for overprescribing opioids.[35] A "full investigation" was defined as going beyond initial factfinding (i.e., beyond merely sending a letter of inquiry to a physician or reviewing pharmacy records). For example, one respondent explained that whenever his board received a complaint against a physician related to opioid prescribing, the board conducted a preliminary investigation during which it typically requested a two-year profile from the state pharmacy board to look at the general prescribing practices of the physician. If they saw a pattern of inappropriate prescribing or had received "a series of complaints over the years that point[ed] to there being a problem," this would trigger a full investigation. Six respondents stated that their boards fully investigate all complaints related to opioid overprescribing.

State pain guidelines, statutes, regulations, or policies were mentioned as providing guidance for when to proceed with a full investigation of a physician for overprescribing. All but six of the boards responding to the survey currently have some form of guideline (sixteen), statute (fifteen), regulation (twelve), or policy (nine) related to pain management.[36] For many boards, if a complaint was made against a physician who was found not to be in compliance with the board's pain rules/guidelines, this would trigger a full investigation of that physician. Comments included: "if we don't have good documentation, if it doesn't appear that the physician's following the board's guidelines with respect to prescribing for pain, then we'll investigate"; "for the most part we adhere to [our pain guidelines].... [we've made] a lot of progress ... teaching physicians how to do this appropriately. We set the minimum standard of care in any state, documentation, informed consent, proper referral, etc., so we look for that"; and "the general policy that was made known to physicians is that we leave prescribing and pain management control issues to their professional judgment, but if there is a complaint, they better have proper documentation, such as informed consent, history and physical, monitoring, etc."

Some respondents commented that the volume or amount of opioids prescribed by a physician might trigger an

investigation — for example, if there were "large numbers of patients receiving large numbers of opioids from the same individual who was seeing patients from a large geographic region, that would trigger an investigation." Also, "if there were extremely large dosages [prescribed], that would make [the board] question if the patient could safely consume that much." However, if there was evidence that backed up the need for the amount of opioids prescribed, most boards would not investigate further (e.g., "if we determined that they were providing therapeutic interventions, then we would close the investigation"). One respondent provided the following example:

> If a person [has] had low back pain for the last 12 years and has been taking long-term increasing doses of pain medicine over the years, and the family is reporting it because [their family member is] an addict now, that would be investigated. Any allegation that the pain is not sufficient to warrant the prescribed opioid [would be investigated], so if it's a cancer patient, no one will argue with that.

Another commented:

> If we get a complaint that a doc's prescribing OxyContin 80 mg four times a day or three times a day,[37] we'll ask the pharmacist if it's a cancer patient. Sometimes the pharmacist doesn't know, but ... if they tell us it's not a cancer patient, it's more than likely the doc will get investigated. Numbers are certainly an indicator, but they're not the only indicator — it's hard to answer with a straightforward answer. Every case has a different twist to it.

In the absence of a board pain management policy or guideline, decisions about investigating or disciplining a physician were often based on deviations from the recognized standard of care. For example, a respondent from a state that had contemplated but not yet adopted pain management guidelines stated:

> [An investigation is triggered by] the deviation from an accepted norm — if someone is prescribing differently from their peers in a specific specialty. As an example, the pain management people will write 10 times the amount of opioids as others. We wouldn't waste time with that person. But if a physician's billing as an internist and prescribing the same as a pain management person, we're going to go find out why. And if the pain management person is prescribing way above others, we'd check that out too. Deviations from a norm we observe, but we don't establish the norm.

Another commented:

> [We're] looking at complaints and poor charting, [cases where] the patient "lost the prescription" and the doctor writes another, but there's no documentation of diagnosis or follow-up, etc. The physician's probably gotten on lack of documentation — we can't prove fraud or diversion, but we can prove good medical practice standards were not [maintained].

Several references were made to using judgment in each case:

> You have to apply judgment; this is not an area that lends itself to cookbook approaches. You have to react to good intelligence, for example, a reliable source like a pharmacy or another health care provider — their threshold to report to the board is high. We review DEA reports for excess purchases monitored, but pure volume doesn't necessarily indicate a problem. You have to tell whether it's below standard of care, not just volume.

In addition to the volume of opioids prescribed, the credibility of the complaint source, and whether there is documented compliance with the pain management standard of care, board policies or guidelines, or state regulations and statutes, boards look at the egregiousness of the physician's conduct. One instance of highly egregious conduct may be sufficient to warrant a full investigation and subsequent discipline, whereas with milder forms of physician misconduct, a board may look at the number of complaints and evaluate patterns of inappropriate prescribing or practice. The uniqueness of each case was emphasized by many respondents. Comments included: "each case is done on an *ad hoc* basis; it depends on who is reporting, what the allegations are, how egregious [the physician's conduct was], the past history of the doctor, etc." and "It's not a simple answer; there's no quota system that a specific amount of drug means you're ripe for investigation. We're looking at a number of aggravating factors."

In some states, medical board investigators worked closely with law enforcement, and thus looked closely at the quality of evidence collected against a physician (e.g., witness testimony quality, corroborating evidence — for example, if anyone observed the physician improperly prescribing opioids — hospital records). One respondent stated: "partnership with law enforcement is a very productive way to run an investigation. They're more expert on the criminal side, more able to identify witnesses — like people who get sex for drugs don't want to testify, but police have ways to find willing victims to come forward."

Discipline for overprescribing

When asked whether respondents thought the number of physicians in their state who had been disciplined for overprescribing opioids had increased, decreased, or stayed the same in the past 5 years, fifteen (39.5 percent) thought the number had stayed the same, fourteen (37 percent) thought it had increased, six (16 percent) thought it had decreased, and three had no real impression (see Table 1). Reasons given by those who thought the number had increased included *an increase in numbers across the board* ("our general numbers have increased" and "everything's gone up; discipline for prescribing violations has not increased more as [a] percentage of the total, we're clearing [backlogged cases] more quickly, we streamlined our processes"); *increased awareness* ("it has to do with increased public awareness, increased awareness on our part; OxyContin is more realized by all of us," and "there's generally a greater awareness in the professional community and the public about this issue now"); *an increased level of sophistication among drug diverters/abusers* ("people are more sophisticated about getting drugs"); and *increased scrutiny by the medical board* ("I think we're more aggressive in taking action because the information is available to the doctors about proper prescribing practices"; "I would think it's ... increased due to increased vigilance. Members of the board are on the lookout for that"; and "the board is paying more attention to these issues, investigating them more seriously, that's my impression").

Reasons given by those who thought the number of physicians disciplined for overprescribing had decreased over the past 5 years involved the redefinition of "overprescribing." Respondents explained: "the board's attitude has changed; now we have pain management guidelines and have an established way of determining if a physician is deviating from those guidelines. We're more aware of the need for adequate pain management and how that should be documented"; "Because the quantity of opioids thought to be appropriate has increased tremendously, those who used to be disciplined now are not considered in violation. The upper limit has been raised, and we're okaying quantities now [that are] four to six times greater than before"; and "I think we were more restrictive than we are now. Now we recognize the necessity for pain management.... [There's] increased vigilance but an acknowledgment that pain management is necessary. We have a policy and pain management guidelines now." Another respondent described a move by the board toward a more proactive approach that averts the need for disciplinary action:

> [W]e utilize other types of informal processes to try to address a [physician] before a pattern of bad practice is established.... [W]e identify [a physician who] ... needs further education but hasn't established the [bad] pattern or egregious conduct — we move some of those through [a special program that is proactive rather than reactive].

One respondent identified being more proactive with opioid prescribing issues as a goal that his board was moving toward: "I don't think the board has been looked at as being proactive; they've been seen as more reactive, so we're trying to change that. It's hard, though."

Respondents were asked what factors would determine whether their board would discipline a physician for overprescribing opioids. Several respondents commented that each case has a unique combination and presentation of facts, making it difficult to identify specific infractions that would automatically lead to a physician's being disciplined — use of individual judgment was necessary. Comments included: "The board doesn't have any policies or procedures on this. We would look at it on a case-by-case basis"; and "We look for records, tests, documentation, etc., and [the board] make[s] a decision about discipline. Our practices are very subjective." One respondent explained:

> We rely on expert testimony. We would consider the harm to the patient, whether the doctor is board-certified, how long the doctor's been in practice, whether there's been any prior discipline, or whether [there's been] any fraud or financial exploitation, the severity of the problem, how long it's been going on, which drugs were used, was a patient harmed — it wouldn't have to be more than one patient, though typically it is — and whether or not the physician was impaired. [If the latter, the physician would go to rehab and the board] might not discipline.... The goal is protecting the public and rehab'ing physicians. You don't always need discipline to achieve that.

There was generally less subjectivity and inconsistency involved in criminal diversion cases ("[The board is] pretty consistent; we usually get a drug profile, get records, get DEA or police to investigate that, make a criminal arrest or investigate, and get an emergency suspension for 90 days ....").

For many respondents, violation of a medical standard of care was enough to warrant disciplining a physician for opioid overprescribing ("there's no need for a pattern or more than one case. One act or omission failing to meet the guidelines or standard of care is enough if the facts are corroborated," and "the standard really is whether the physician is practicing below the standard of care and whether there's a continued pattern of irregular or substandard care. We usually don't have a problem with showing a pattern, and if the physician is below the standard of care, we're quick to bring action"). Others commented: "we'd discipline based on failure to meet generally acceptable standards

of practice; usually it's based on poor recordkeeping, [rather than] 'overprescribing opioids'"; "it's based on adherence to medical standards of practice, and proof of that in documentation."

Respondents mentioned various things they looked for when investigating physicians for violating the standard of care for overprescribing opioids, including poor maintenance of patient records/poor documentation, "upcoding third party billing from a routine to a sick visit when [the visit is] under five minutes — usually you don't even find a blood pressure [charted] — significant findings of another disease entity not being followed, like hypertension or hyperlipidemia, not monitoring or following up," "red flags in the [patient] record like lost meds.... [I]f we see a lot of that stuff, we start to think the doc doesn't know what he's doing. Especially whether the doctor refers out or not [to a pain specialist],"[38] "ongoing monitoring, discussion with the patient ... in general, an absence of appropriate documentation to substantiate their professional decision." One respondent reflected on how the pain management standard of care has changed:

> What used to be called overprescribing 5 years ago is not that now. There's been a change in the field of pain management. Now we don't discipline for quantity only. The thinking has changed in the practice of medicine. Now we are focusing basically on any practice that could be harmful to the patient, and this is based on standard of practice, which has changed.

However, a few respondents mentioned that standard of care violations would typically not be disciplined by their board, at least not without a demonstrated pattern of infraction by a physician ("we have to see a pattern"; "it would have to rise to negligence on more than one occasion, or inappropriate treatment; we'd have a hearing, there'd be due process, it would have to be a pattern that was established"; and "obviously, any case where we see a pattern of patient harm, willful and repeated violation of prescribing laws and regulations, we'll discipline. But we'll probably try to educate the doc"). One respondent stated:

> It depends on all the facts, the pharmacy printout, and we look at the patients — sometimes they doctor shop. But if it looks like the doctor was fully aware that the patient may have an abuse problem and [s]he continued to prescribe, or was asked by the board to take a prescribing course in the past ... if after that the physician is still doing the same kind of thing, we'll step up the disciplinary process.

Boards that had adopted pain guidelines referred to them in making judgments about a particular physician's actions. One respondent stated: "We look to [our pain rules] to give us guidance as to whether there's a violation. We tend to [apply] formal disciplinary action with doctors who have shown egregious conduct or established a poor pattern of practice." Another commented:

> We refer to our pain guidelines. It's not based just on dose but quantity. We realize that people are in pain and need medication for that, but there comes a point where it's not physically possible to consume so many opioids in such a short period of time.

One respondent explained the benefits of referring to a position statement when enforcing opioid prescribing standards for physicians:

> We set up the position statement against legal advice, because it doesn't have the same legal standing as a law or rule, but it allows us to articulate the standard of care in each instance. Expert testimony is then used when prosecuting a physician to show that he did not follow the articulated standard. For example, the position statement says you have to see the patient before prescribing drugs for them. This rules out Internet prescribing. We've gone after four docs for prescribing over the Internet without seeing patients first, and we upheld that through the position statement. But the position statement allows us to discriminate [about] when to go after docs. We don't have to go after everybody.... The position statement allows a physician to treat pain, that's standard of care, but it does say that the physician needs to comply with the minimum of appropriate medical practice.

The most common form of sanction imposed in overprescribing cases was mandatory education/retraining. Other sanctions included (listed in order of frequency mentioned): license suspension, license revocation, probation, restriction of opioid prescribing, monitoring of prescribing practices, mentoring and supervision, reprimand/censure, and a fine. One respondent stated:

> We classify our drug problems into three categories: failure to follow [standards of medical practice], diverting drugs for self-use, and diverting drugs for money, sex, or other things. We take a very different tack for all three. For the first, we retrain. For the second, we rehab. For the third, we have no patience.

Other comments included: "[the sanction] depends on the severity of the offense, frequency, contrition and recognition

on the part of the practitioner, whether he's been before the board on an offense"; "I couldn't say, there's such a range — everything from revocation to public censure to nothing [to] rehab"; "the sanctions differ depending on the case"; and

> I don't always get the sanctions I want. I would like to see temporary suspension of a license and mandatory attendance at an appropriate prescribing workshop. The sanction has to have enough meaning to get their attention. Many can write a $10,000 check and they don't miss it.... You've got to take them out of the loop a little while, get their attention big time.

Another respondent explained:

> If it's limited to a lack of knowledge, we have a lot of tools to evaluate what to do.... [I]f it's a pretty big problem, we send them to get a report on their skills/knowledge.... [I]f it's a minor knowledge base [problem], we send them to a remediation program.... If there are other quality of care issues, we send them to an evaluation program. Then with doctors trading drugs for sex, that's a character problem; we would invoke long-term [license] suspension or revocation.

Opioid underprescribing: Complaints

Nineteen respondents (50 percent) were aware of complaints to their board against physicians for undertreatment or inadequate treatment of pain in 2001. Based on the thirty-three respondents who were able to estimate the number of complaints, the average per 1,000 doctors in the state was 0.46 (standard deviation = 1.1, range = 0 to 5.9).[39] The major source of such complaints was patients (eight respondents identified nonprisoners as the major source, two identified prisoners, and five reported both prisoners and nonprisoners).[40] The other primary source of complaints was family members (nine out of nineteen). One respondent explained: "[There are] three major sections that prescribing complaints can fall under: unprofessional conduct, incompetence, and fraud. [Inadequate pain management complaints are] usually in the first two categories." Some felt this problem was underreported ("it's a very underreported problem, in my opinion"; and "I've had orthopods proudly say they've never written for a Schedule II, and my question is 'Why? Aren't you dealing with people with severe pain...?' So I'm sure there's undertreatment, we just don't see the formal complaints."). A few respondents did not perceive undertreatment of pain to warrant a serious response by the board ("[we've received] just a few [complaints about undertreatment of pain]. Normally those were dismissed or no action was taken because the board doesn't perceive that circumstance as a real high threshold of some kind of negligence or incompetence."). Others demonstrated a commitment to the issue, despite the absence of complaints ("as a cancer survivor I'm sensitive to the issue, but I don't see complaints from cancer patients saying the doctor didn't treat my pain carefully" and "I've kind of looked for them, but haven't found any so far.").

A few respondents gave examples of inadequate pain management complaints as being revealed, through investigation, to be instances in which patients were actually receiving adequate doses of opioids or were addicted to opioids and then complaining that they were cut off from their source of drugs. One respondent explained:

> We did have one doctor who was overprescribing her patients who were addicted to narcotics, and after we suspended her license, some of them called to complain they couldn't get their meds, but those were [addicts trying to get narcotics, so it's not a legitimate complaint of undertreatment for pain].

Twenty-seven respondents (71 percent) thought there had been no change in the number of complaints the board had received in the past 5 years regarding inadequate treatment of pain. Six respondents thought there had been more complaints, and two thought less. Three had no opinion. Those who thought the number of complaints had increased attributed it to increased public awareness ("on a personal level I find [awareness about this issue to have increased] in hospitals; my husband recently had surgery and they were constantly asking him about pain — having him score his pain every time you turned around").

Investigations and discipline for underprescribing

Respondents were asked to estimate the number of investigations their board had *ever* conducted related to pain undertreatment. Nineteen respondents thought their board had never investigated a physician for undertreating a patient's pain, and sixteen thought their board had. (Three did not know.) Of the latter sixteen, eleven were able to estimate the number of investigations their board had ever conducted related to undertreatment of pain. The average number of investigations was 1.7 (standard deviation = 3.4, range = 0 to 13). Six respondents said all the cases involved nonprisoners, three said they involved only prisoners, and three said both prisoners and nonprisoners. Four did not know. One respondent pointed out that physicians are not required to "treat every patient who comes in the door," so a physician may refuse to refill a new patient's request for opioids — this is different from a physician failing to treat people under his or her care. Only one board had actually disciplined a physician for undertreatment of pain.

Respondents were given facts from the case regarding Dr. Bilder, the physician who was disciplined by the Oregon Medical Board for undertreating his patients' pain. Seventeen respondents were familiar with the case, ten were not, and eleven were unsure. When asked how likely the respondent's board would be to take disciplinary action against a physician for whom the board had received similar complaints that were later corroborated, eleven respondents thought it was almost a certainty (i.e., greater than 90 percent), fourteen respondents thought it was probable (60–90 percent), three thought it possible (40–60 percent), two thought it unlikely (10–40 percent), and three gave other ranges (between 60–100 percent, and between 40–90 percent). Five could not say.

Respondents' comments added further insight. Some stated that their board is limited in the kind of disciplinary action it can take ("the law only allows us to take disciplinary action if they're grossly negligent"; "we have to use clear and convincing evidence to prosecute, and that's a pretty high standard of evidence"). Several respondents commented that each case is unique and it would be difficult to predict their board's response ("it depends on the facts" and "the board tries not to make pronouncements on types of cases because they're dependent on facts and circumstances. The doctor may be making the right judgment in that particular situation, it may be appropriate. There are no cookie-cutter answers for these cases."). Some noted that more than one instance of pain undertreatment would be necessary ("you can't establish a pattern of practice with one patient"). Others looked for level of egregiousness ("The decision would be based on the medical record, and if there was a danger to the health, welfare, and safety of the community, that would definitely be a legal basis for [disciplinary action]. If it was found that the situation was egregious, there would be a legal basis for a summary suspension.").

A number of boards appeared disinclined to consider a standard of care violation alone as a basis of disciplinary action in cases of pain undertreatment ("the board tends not to discipline based on standard of care but on [gross] negligence"). One respondent voiced frustration with this general tendency of the respondent's board:

> My problem here is we see standard of care [violation] cases all the time, but we don't discipline on [violation of] standard of care. For some reason our reviewer ... says, "well, it's not the best medical care, but it doesn't rise to the level of gross negligence." I wonder, what constitutes gross negligence? ... I don't think we do a good job at all on standard of care. I'd like to think so, but we don't.

Some respondents thought that the physician's intent would be relevant ("was he trying to avoid DEA scrutiny rather than intentionally make people suffer?"), implying that a physician's lack of knowledge about adequate pain management would be grounds to evade board sanctions for pain undertreatment ("You would almost have to show criminal cruelty. [Giving Tylenol for cancer pain, knowing it doesn't alleviate the pain,] could show that."). However, a few thought their boards would discipline if they could prove that the standard of care had been violated ("yes, standard of care would be disciplined, depending on the facts"; "we do discipline standard of care issues; it's hard to prove sometimes, but we do"; and "if the physician is just disregarding the patient's complaint [and the patient's] not getting better, standard of care dictates that a follow-up is required and, if [that does] not [happen], then standard of care is not met").

Those whose state medical boards had pain management guidelines or end-of-life legislation used those guidelines, policies, or legislation to benchmark the physician's actions. One respondent stated: "that's just cruel to those patients, and it's not in conjunction with [our] pain management guidelines." Another explained: "our state has pain rules that were made by the board that the physician is expected to follow, and if it was verified that the physician didn't follow them, as would be the case with the physician in this scenario, that physician would most likely be disciplined." Another commented:

> A doctor would have to show a pattern of practice of undertreatment, and following our pain guidelines, if the patient's pain was 10 out of 10 and [he's] giving Tylenol or ibuprofen, that's really ridiculous. Our consultants are in pain management and they believe in treating for pain. [But] it's hard to gauge since we've never [disciplined for undertreatment of pain] before. There are eighteen different personalities on our board, and it's hard to say how they'd go.

Yet another respondent stated:

> In [this state] you're not held criminally liable for judicious titration in cancer patients, so to get an undertreatment case, you just have to have a real lack of education, and if we saw that, we'd have to utilize some discretion. Why did it happen? Can the physician be educated without sanction and still protect the public?

Several respondents thought that, depending on the facts of the case, a physician would likely be educated about pain management before sterner sanctions were invoked. One respondent stated: "they wouldn't suspend a doctor's license probably, they would probably want re-education. Some of those programs here are very expensive, but the board doesn't let that stop them from recommending such a course." An-

other explained: "if it was an innocent mistake … and if there was no pattern … the remedial board would review another 10–20 charts of that doctor, in a very collegial way, and tell him what he needs to do, and [make it clear that] 'we don't want to see you again.'" One respondent wondered whether sanctioning a physician for undertreating pain would lead to overprescribing problems ("once you discipline someone … they can go the other way. I've had physicians say, 'Fine, I get disciplined for not doing it, I'll give everybody drugs.'"). One respondent thought, "If you're just coming in and spanking people, [that's not helpful] … doctors [need] good messages, too…. Our goal isn't just to discipline as much as we can." However, other respondents thought their board was too lenient in dealing with physicians for undertreating pain.

Use of pain management experts

Respondents were asked whether their board ever used a pain management expert to assist with an investigation involving the prescribing of opioids (either underprescribing or overprescribing). Thirty-one respondents said their board had used such an expert. The mean percentage estimate of cases in which a pain management expert was used was 29.2 percent (standard deviation = 35.0, range from 0 to 100 percent).[41] This result must be interpreted cautiously, as some respondents qualified their answer by stating that the denominator of their estimate was investigations involving opioid prescribing for pain management, not opioid prescribing for criminal cases (e.g., physicians illegally prescribing opioids in exchange for sex or money, or self-prescribing). One respondent explained: "we have pain management guidelines that we've published, and it's easy to compare a physician's behavior to those guidelines, but I'd say we refer to a pain management expert in about 20 percent of the investigations, but they [also] use our guidelines." Another stated: "in a case right now we're using a pain management expert, but that's only the second or third time. Usually the cases are pretty clear." Some respondents stated that their boards use a pain management expert whenever disciplining a physician for opioid prescribing practices, or whenever the board has a hearing in which someone testifies against the physician for issues related to opioid prescribing. One respondent explained: "if the nexus of the case is pain management, then a pain management expert is involved." One respondent noted that recent legislation required that a palliative care physician sit on the board. Another stated: "with our budget problems, [we don't use a pain management expert] as often as we'd like ([only] about 20–25 percent [of the time]). [There's] a pretty good mix of physicians on the board and subcommittee. They usually do okay, but sometimes they need the expert."

When asked to name the credentials of the pain management expert used, five respondents mentioned board certification in anesthesiology, twelve mentioned certification in pain management (mostly through anesthesiology pain management certification), seven mentioned experience-based expertise ("usually it's a doctor who's well-respected in the community and works for a pain clinic or runs a pain clinic"), and one mentioned a combination of experience-based and pain-management-credentialed expertise. Six did not know. Several mentioned that they try to match the specialty area of the physician being investigated with that of the consultant ("If it's a family physician, we look for a family physician who also treats chronic pain patients."). One explained: "very few physicians are board-certified in pain management, [but] there are a lot who practice pain management. We would get an internist if an internist was involved, etc." Another reiterated: "few people are certified in pain management, though most [experts] we use, that's their main specialty. They advertise themselves as pain management experts. Most are board-certified in their primary specialty at least. A handful are board-certified in pain management, but not a lot."

Potential chilling effect

Several respondents commented about the potential chilling effect that could be created by the board's investigations of and disciplinary actions against physicians for opioid prescribing. Some wondered how these fears were propagated. One commented: "the thing that surprises me is that physicians won't prescribe because they say they will get in trouble from the state. Where do they get this idea? … It's always baffled me where they get that from. Urban myth." Another stated: "there's a perception by many GPs or internists that we are something much bigger than we really are. It's the Big Brother syndrome, like the IRS, a bigger perception than many of us in the regulatory business are really aware of." Others thought there might be some truth to such concerns, as is conveyed in the following comment:

> It has gotten out that the board is very active and this has created the feeling of some in the medical community that we're out to get them. And some have asked me if I'm worried that we're being too aggressive, and I do worry about that. But I worry too that they'll forget we're here.

Another responded similarly, emphasizing that the interest in avoiding a chilling effect must be balanced with the board's obligation to protect patients from harm:

> Doctors like to cry foul anytime we inquire about anything, and say we've scared them so they're not going to prescribe anything. It's just a problem we have to deal with on a case-by-case basis. There are doctors out there who are harming their patients, and we have to protect the patients too.